

APPENDIX C7
SUBMITTAL AND APPROVAL OF ALTERNATIVE TRU WASTE
CHARACTERIZATION ANALYTICAL METHODS





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C7-1 Purpose and Scope

The National Transuranic Program (NTP) Organization provides the *Transuranic Waste Characterization Sampling and Analysis Methods Manual* (Methods Manual) (DOE 1995a) for use when characterizing transuranic (TRU) waste. However, the NTP recognizes that new or modified techniques may be needed to meet performance objectives for specific wastes and to minimize waste generation associated with sampling and analysis. The NTP has developed a written procedure for guidance to the analytical laboratories at the generator site who want to submit an alternative analytical method for approval by the NTP.

The procedure provides an initial approval process, a list of minimum performance data required for approval of the alternative method verification, and the process of method acceptance. It includes method format specifications, documentation, and supporting data required as part of requests for alternative method approval.

The *Transuranic Waste Characterization Quality Assurance Program Plan* (QAPP) (DOE 1995b) establishes a performance based program where quality assurance objectives (QAO) are defined for all analytes. The Methods Manual contains approved methods with demonstrated performance data that meet the QAOs and should be used if possible. The TRU Waste Characterization Interface Working Group (WCIWG) is responsible for the review and recommendation of alternative methods to the NTP (DOE 1995c). Final approval of alternative methods will not be granted unless the QAOs described in the QAPP have been met.

C7-2 Preliminary Approval

The preliminary approval process is used to screen the number of alternative methods requiring review and approval. The approval must be obtained in the planning and initial testing stages of the method development process to avoid duplication of efforts and conserve time and resources. To obtain the preliminary approval, the author must submit a written description of the method, with justification and supporting documentation, to the NTP Waste Characterization Manager at the Department of Energy Carlsbad Area Office (DOE/CAO).

The method description must be complete enough so that the technical applicability can be assessed. Any limitations of the method must be clearly stated. Criteria for appropriate justifications are: 1) previous analytical data supporting the fact that existing or approved methods cannot be used (e.g., a radioisotope creates an interference), 2) data supporting the fact that an approved method cannot meet the QAOs for a specific matrix, or 3) information demonstrating that an alternative analytical method offers a distinct advantage over the approved methods, such as waste minimization, reduction of analytical time, or reducing worker radiation exposure.

When submitting justification statements in cases of waste matrix interferences that prohibit compliance with required QAOs, the author must demonstrate with supporting data that: 1) the laboratory personnel can satisfactorily analyze other less complex matrices (e.g., water) using an existing approved method, 2) the analyte or matrix interferences from the specific waste is the cause for nonconformance with the QAOs, and 3) there is sufficient evidence from literature or other studies that support the potential use of this alternative method for this waste.

A description of the method will be posted on the WCIWG bulletin board in the Analytical and Test Methods Development Forum to enable the review committee to seek input from other sites. In addition, other sites may comment with supporting data or additional information that will aid the review committee.

C7-3 Required Elements of Alternative Methods

When a method is submitted for approval, all twelve sections of the method, as presented in the Methods Manual, must be included. Tables, figures, flowcharts, equations, units, nomenclature, and references must be clearly labeled and follow the Methods Manual format. The performance criteria must apply to at least one matrix, and the actual method must have been successfully tested on simulated or actual waste samples.

Minimum performance data, demonstrating compliance with the requirements of the QAPP, must be provided for each waste matrix for which the method is to be used that consists of:

- A detection limit study including the statistical method for calculation (seven spiked replicates)
- A precision and bias study using spike and replicate samples of the matrix of interest or similar matrix
- A method blank study using reagents and equipment to ensure contamination will not be a problem
- Data demonstrating the QAPP QAOs are met for accuracy and precision (spike, duplicate, and replicate measurements)
- An interference study using waste matrix spikes

C7-4 Final Approval

A review committee for review and approval of proposed methods will be assembled by the WCIWG chairperson. The review committee will be composed of individuals with expertise in the field of the proposed method. The review process includes determining the applicability of the method; reviewing the performance data, quality control sample requirements, and acceptance criteria, bias and interferences; and checking the equations and calculations. The data that demonstrate results, sensitivity, and repeatability also will be reviewed and checked for accuracy and completeness.

A formal comment and response process will be documented to provide for the clarification of issues relating to the methods and performance data. This also ensures that methods undergo a comparable review process and obtain equal consideration. In some cases, additional performance information, Quality Control data, or more investigation will be required before approval. In other cases, the method may not be approved because the QAOs were not met. In either situation, the method author is allowed one written challenge to the WCIWG review committee's decision.

After the method has undergone WCIWG committee review, all reviewer's comments have been satisfactorily resolved, and the final changes have been made to the method, the method is submitted to the DOE/CAO Quality Assurance Manager for concurrence. After concurrence, the method will be submitted to the DOE/CAO Regulatory Compliance Manager for review and approval. The DOE/CAO Regulatory Compliance Manager will submit the proposed method to the New Mexico Environment Department (NMED) for concurrent review. Upon completion of its review of the proposed method, the NMED must provide a written statement that the method is acceptable, or written comments to the DOE/CAO Regulatory Compliance Manager. The DOE/CAO Regulatory Compliance Manager will notify in writing the WCIWG chairperson regarding whether the method can or cannot be used for TRU waste characterization. Methods approved by both the DOE/CAO Regulatory Compliance Manager and the NMED will be incorporated into the Methods Manual. Methods not approved by the DOE/CAO Regulatory Compliance Manager or found unacceptable by the NMED will not be incorporated into the Methods Manual until all comments have been resolved. Also, the availability of approved, alternative methods will be posted on the WCIWG electronic bulletin board in the TRU Waste Characterization Methods Manual Protocols Forum (DOE 1995d). As additional performance data are generated, these data are also made available through the bulletin board to ensure the most current information is available to the generator sites. Records associated with this review and approval process will be kept on file by the DOE/CAO and will be available for review.

C7-5 References

DOE. 1995a. *Transuranic Waste Characterization Sampling and Analysis Methods Manual*. DOE/WMP-91-043, Current Revision, Carlsbad, New Mexico, Carlsbad Area Office, U.S. Department of Energy.

DOE. 1995b. *Transuranic Waste Characterization Quality Assurance Program Plan*. CAO-94-1010, Revision 0, Carlsbad, New Mexico, Carlsbad Area Office, U.S. Department of Energy.

DOE. 1995c. *Waste Characterization Interface Working Group Charter*. Carlsbad, New Mexico, Carlsbad Area Office National Transuranic Program, U.S. Department of Energy.

DOE. 1995d. *TRU Waste Characterization Interface Working Group Communications Plan*. May, 1995, Carlsbad, New Mexico, Carlsbad Area Office, U.S. Department of Energy.