P801 Statement of Work

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This policy outlines the requirements for human tissue and bone sample preparation services provided to USTUR by a contract laboratory.

Introduction

The United States Transuranium and Uranium Registries (USTUR) program is unique in providing direct information on the distribution of the Pu, Am, and U in the tissues and bones of occupationally exposed human subjects, based on radiochemical analyses of said tissues and bones. It is most important that the data obtained be of high quality for modeling purposes as well as being legally defensible.

The USTUR requires tissue and bone sample preparation services (ashing and dissolution) in support of USTUR radiochemical bioassay analysis activities. This statement of work (SOW) outlines the requirements for tissue and bone sample preparation services provided to USTUR by a contract laboratory.

USTUR materials will consist of bioassay samples to include human soft tissues and bone. The sections below detail specific protocols and procedures; deliverable formats, and schedule requirements. These conventions have been established to ensure that USTUR data quality objectives (DQO) are met.

The contract laboratory shall perform all sample preparation work received from the USTUR. No secondary laboratory shall be employed for USTUR work.

In general, a qualified, full service laboratory is preferred to simplify sample shipment and ensure delivery schedules are met. The laboratory may also submit proposals for radiochemical analysis services.

The contract laboratory shall develop and implement a documented program consistent with USTUR requirements.

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CHAPTER 1: TISSUE PROCESSING REQUESTS AND SAMPLE SHIPMENT

1.1 Sample Batch Orders

The contract laboratory will be notified by USTUR via e-mail or telephone contact to expect a sample batch shipment. The type and number of samples in the shipment, and the requested work, will be defined in the USTUR Sample Dissolution Log (attached as Appendix A). This will be sent electronically to the contract laboratory prior to shipment. A hard copy of USTUR Sample Dissolution Log will be enclosed with the sample batch shipment. The completed USTUR Sample Dissolution Log shall be returned by the contractor electronically and a hard copy form enclosed in the return shipment to USTUR.

1.2 Sample Custody

Sample custody is transferred to the contract laboratory at the time of sample receipt, after which the contract laboratory is responsible for maintenance of unbroken chain of custody (COC). By definition, a sample is in custody if it is 1) in one's possession, 2) in view, or 3) in a controlled access area. Section 2.9 of this document provides additional detail regarding sample receipt procedures.

1.3 Shipping Charges

USTUR shall typically pay sample shipping charges. However, it may become necessary on occasion to ship samples collect. In such cases, the contractor shall be reimbursed for the shipping charges. Collect-shipping charges shall be included in the invoice for the associated delivery order.

1.4 Itemized Processing Charges

Unit prices provided by contract laboratories shall include the cost sample ashing and acid dissolution, cleanup, reporting, and temporary storage requirements specified in this SOW. Accelerated turn-around times are discussed in Section 4.3.1 of this SOW.

1.5 Time Definitions

References to days, weeks, or months are defined as calendar days, weeks, and months unless otherwise specified. Report delivery schedules are specified in Section 4.2 of the SOW.

CHAPTER 2: USTUR GENERAL REQUIREMENTS

2.1 Methods and Documentation

The contract laboratory must prepare complete documentation for every activity in order to facilitate review and enhance defensibility of the process. Documentation requirements include records for sample receipt/login, chain of custody (COC), preparation and digestion. Sample batch documentation must be provided by completion of USTUR Sample Dissolution Log (Appendix A).

2.2 Deliverables

USTUR requires electronic data deliverables (EDD, as shown in Appendix A) at the conclusion of each delivery order. Contract laboratories will provide line item pricing for each type of report in the schedule of charges submitted to USTUR. Data deliverable requirements are fully outlined in Appendix A.

2.3 Compliance

Contract laboratory must be in compliance with applicable local, state and federal regulations for the receipt, handling and disposal of waste from dissolution of human soft tissues and bones.

2.4 Contract Laboratory Requirements

2.4.1. Specific Requirements

- Table of contents
- Contract laboratory organizational structure and key personnel responsibilities.
- Personnel training, with required training, frequency, and methods of records maintenance specified.
- Sample receipt, custody, and management practices.
- Facilities and equipment, including a description of security procedures, sample storage practices, and a list of equipment available in support of the USTUR program at the contract laboratory. Equipment lists shall include acquisition dates.
- List of all SOPs applicable to USTUR program by number and matrix. Contract laboratory policy shall require that controlled copies of these SOPs be available to the laboratory staff.
- Title page with provision for approval signatures, dates and revision of SOP for ashing and dissolution of human tissue and bone.
- The dates and calibration records for any equipment (analytical balances, ovens, freezers, etc) used in a dissolution process for USTUR referencing SOPs for these calibration procedures.
- Any unusual occurrence (UOC) must be reported in a form of a narrative with suggested corrective actions to USTUR.
- The data review and approval shall be made by peer, supervisory, or USTUR Project Manager (PM).
- The list of approvals and certifications from states and external agencies for the receipt, handling and disposal of waste from dissolution of human soft tissues and bones shall be appended to the USTUR report.

2.4.2. Report Verification and Format

- A contract laboratory SOP shall discuss methods for verification of EDD and hard copy agreement for sample identifiers, dry and ash bone weight, acid usage, final solution weights. If applicable results from total a-counting of filtered material are to be reported with counting uncertainties.

- The contract laboratory policy regarding the number of significant figures shall report with 2 decimal places (12.01, 100.06, 506.56 g).

2.4.3. Standard Operating Procedures (SOPs)

Complete and comprehensive SOP's applicable to ashing and dissolution of USTUR's human tissues and bones, including any supporting SOP's (e.g., measurement of filtered material).

2.5 Internal Audit Requirements

The contract laboratory shall undergo an audit by USTUR personnel at least once per year. The purpose of this audit is to verify contract laboratory compliance with the specifications of this SOW and its own SOP, COC peer-review activities in regard to USTUR work. In addition, recommendations may be made to contract laboratory personnel regarding possible quality improvements in light of good laboratory practices and/or industry standards. A formal audit report will be issued following this activity. Responses to audit reports will be due 30 days from the date of issue.

2.6 Employee Training and Documenting Employee Proficiency

Once SOPs for the USTUR program have been developed and documented, contractor laboratory personnel shall have documented training and experience with specific procedures they assigned to perform. Evidence files must exist to demonstrate that each employee has met the contractor's training requirements and has read, understood, and is using the latest version of the contactor laboratory's SOP's related to the USTUR program.

Training on specific equipment, analytical techniques and laboratory procedures shall be documented.

Personnel that have not been trained and evaluated shall not participate in the handling process of USTUR samples.

2.7 Contract Laboratory Instrumentation, Equipment, and Reagent Maintenance

2.7.1. Instrument Logs and Response Checks

The contract laboratory shall maintain an instrument logbook for all major instruments used to acquire data for USTUR. Each instrument logbook shall be clearly labeled to indicate its association with a particular piece of laboratory equipment.

The contract laboratory shall record the data file names and dates for all calibration activities in the associated instrument logs. Documentation shall be provided for the measurement of any USTUR material (e.g. filtered insoluble matter) by gas flow proportional counting (GFPC).

2.7.2. Balances and Sample Storage Refrigerators

Contract laboratories performing digestion of USTUR samples shall have a calibration SOP of analytical balances. The SOP shall specify that balances be checked against certified standards and that balances not accurate to within at least ± one percent be recalibrated or removed from service. The contract laboratory shall maintain logbooks in which the analytical balance calibration checks are recorded.

2.7.3. Reagent Water Production

Contract laboratory shall have an SOP for reagent water or DI water production and system maintenance (e.g. ASTM Type II water). This SOP shall outline specific control criteria for reagent or deionized water quality and give specific corrective actions to be taken for out-of-control events. Records of water quality shall be kept in logbooks designated for that purpose.

2.7.4. Control of Reagents and Stock Solutions

The contract laboratory shall have an SOP outlining policy on shelf life, labeling, and stock maintenance for reagents and stock solutions.

The SOP shall require that acid dilutions be prepared using ASTM Type II water, at minimum.

The contract laboratory should document the manufacture, chemical grade and manufacture batch number, concentration or % of all vendor-supplied reagent chemicals that are used in dissolution of USTUR samples.

2.7.5. Incident Tracking

The laboratory shall have a system for recording and tracking incidents involving loss of client samples. Such incident should be reported to USTUR. The tracking system may be implemented through facilities, H&S, QA, or other laboratory groups.

2.8 Standard Operating Procedures for Tissue and Bone Ashing and Dissolution

2.8.1. Control of Standard Operating Procedures

The contract laboratory shall maintain controlled copies of approved SOPs for each method used for tissue and bone dissolution performed by contract laboratory personnel. The contract laboratory shall set and demonstrably adhere to a schedule of periodic review of SOPs. Changes in contract laboratory SOPs that significantly affect the dissolution of USTUR samples shall be transmitted to the USTUR for approval prior to implementation. Laboratories may seek approval by telephone for minor SOP modifications.

2.8.2. Availability of SOPs

Controlled copies of SOPs shall be readily available to all personnel performing ashing and dissolution work in support of the USTUR.

2.9 Sample Receipt and Storage Requirements

2.9.1. Communication before Sample Receipt

USTUR will notify the contract laboratory project manager via e-mail or telephone contact to expect a sample shipment, the type and number of samples in the shipment, and any special requirements (rapid turnaround)

2.9.2. Sample Chain-of-Custody (COC)

USTUR samples are packaged and placed in shipping containers. The shipping containers are usually shipped via Federal Express for overnight delivery to the contract laboratory.

A COC form will accompany USTUR samples received by the contract laboratory. The COC will be enclosed in a plastic envelope inside one of the shipping containers.

At the time of sample receipt, this form will have been partially completed by the USTUR staff, and should indicate the contract laboratory name, shipper number, sample IDs, sample matrix, date shipped, and any special hazards information.

2.9.3. Acknowledgement of Sample Receipt

At the time of receipt, the contract laboratory sample custodian shall:

- Sign and date the COC form in indelible ink to acknowledge sample receipt and accept custody.
- Document the batch number associated with the shipment of samples and USTUR assigned ID numbers on the COC.
- Return a copy of the COC form via e-mail to USTUR to indicate acknowledgement of receipt and status of samples.

2.9.4. Documentation of Anomalies

The contract laboratory sample custodian shall note the following on the COC form and sample login worksheets:

- Any irregularities observed with the shipment, temperature, condition, or custody seals of samples received.

Login worksheets shall specifically identify any samples affected by such irregularities:

If no anomalies are encountered for a sample shipment, a brief statement of that fact shall be provided on login worksheets and in the batch narrative.

2.9.5. Communication of Anomalies

A contract laboratory representative shall notify USTUR immediately by telephone of any irregularities noted during the sample receiving process.

2.9.6. Sample Retention

All USTUR dissolved samples shall be retained and stored for a period of 2 weeks. Stored solutions should be checked for possible insoluble material using a Tindal beam (flashlight). Those samples found to have remained in solution may be returned to USTUR.

2.9.7. Sample re-processing

Any sample found to have any insoluble material present must be re-processed at no additional charge to USTUR by the contract laboratory. USTUR must be informed of the SOPs used in the re-processing.

2.1 Contract Laboratory Data Verification and Review Requirements

2.10.1. Worksheet Review

All worksheets describing preparation of USTUR samples shall undergo supervisory or peer review. A field shall be provided on each worksheet for the reviewer's initials. The reviewer need not sign each page of a submittal; only one signature per data submittal (per batch) is required.

Worksheet review signatures signify that the contract laboratory has met the requirements of the method and this SOW.

2.10.2. Report Review

The Sample Dissolution Log transmitted to USTUR by the contract laboratory shall undergo verification and completeness review by the contract laboratory's project personnel. In addition, reviews shall include 100 percent verification of agreement between EDDs and hard copy reports, as defined in Section 2.4.2 of this SOW. Signature evidence of these reviews in the batch narrative is required.

2.11 Contract Laboratory Record Maintenance Requirements

The contract laboratory shall maintain a file for each sample batch and all documents and records associated with each specific delivery order for the duration of the contract period. Alternatively, an effective system ensuring the ability to retrieve all associated records in a timely fashion may be implemented. All worksheets, digestion logs, shipping and login records, custody forms, and communication records must be included in the batch file or addressed by the retrieval system discussed above. This supporting documentation may be used to verify compliance with the requirements outlined in this document, or to support the preparation process in a court of law. The supporting documentation shall be shipped to USTUR or discarded, at the discretion of USTUR, when the contract base period and all exercised extensions expire. Charges for shipping supporting documentation will be reimbursable at cost.

If an electronic data storage system is used, the laboratory shall have an SOP that addresses creating, verifying, and tracking electronic records. The Good Automated Laboratory Practices (GALP) requirements of Section 2.15 of this SOW shall be implemented as applicable, and the records shall be in a format that is readable using common commercial software.

2.12 Corrective Action for Unusual Occurrences

2.12.1. Requests for Corrective Action Reports (CARs)

The contract laboratory may be required to provide a CAR for any unusual occurrences (UOC) associated with the services provided to USTUR.

2.12.2. Delivery of CARs

As described in this of the SOW, initial responses to CAR requests including the projected schedule for completion, shall be due no later than two weeks from the date of the request. USTUR reserves the right to request delivery of CAR responses in less than two weeks if circumstances indicate that this is necessary. Failure to submit requested CARs may result in suspension of the contract laboratory from USTUR laboratory analysis program.

2.13 Quarterly Report Requirement

2.13.1. Contents of Quarterly Reports

The contract laboratory shall submit quarterly reports to USTUR. Quarterly reports shall address calendar quarters and are due by the 15th day of the month following the reporting period. In addition to the quarterly reporting requirement, contractor will notify USTUR immediately for issues relating to changes

in key technical personnel, changes in certification status, and loss of capability to perform as specified in this SOW. Emphasis should be placed on the following for inclusion in the Quarterly Reports (QRs):

- Changes in current SOP related to USTUR program.
- Summaries of unusual occurrences during the reporting period, and copies of the associated CARs.
- Changes in key technical personnel, including resumes of new personnel.
- Changes in certification status with any regulatory or certifying agencies.
- Loss of capability to perform and service that is specified in existing contracts with USTUR.

If no significant changes occurred during the reporting period, and if no CARs were generated, then a simple statement of these facts shall suffice to meet the QR requirement.

2.13.2. Compliance

Failure to comply with the QR requirement in this SOW may result in suspension of the contract laboratory from the USTUR program.

2.14 Primary Contact Person

2.14.1. Contract Laboratory Contact Person

The contract laboratory shall assign a project manager (PM) to be the primary contact person for issues relating to the dissolution of USTUR samples.

2.14.2. USTUR Contact Persons

The Contract Technical Representative (CRT) for USTUR shall be provided to each contract laboratory at the time of contract award or renewal.

2.14.3. Communication

Open communication between USTUR and contract laboratories is crucial to developing a mutually satisfactory business relationship. Contract laboratory PM is encouraged to seek guidance in advance of performing work when any questions arise.

2.15 Good Automated Laboratory Practices

Good Automated Laboratory Practices (GALP) must be used by the laboratories to ensure the reliability of information relayed to the USTUR *via* its Sample Dissolution Log. These include verification of information related to USTUR tissue dissolution.

2.15.1. Laboratory Management

When electronic data are transmitted, or maintained, the laboratory management shall:

- Ensure that personnel clearly understand the functions they are to perform.

- Ensure that personnel, resources, and facilities are adequate and available.
- Ensure that PM monitors computer activities associated with USTUR program.
- Ensure the integrity of electronic information forwarded to USTUR.

2.15.2. Personnel

The laboratory shall:

- Ensure that computer staff have adequate education, training and experience to perform assigned functions.

2.15.3. Information Transfer

The contractor shall designate PM to monitor the transfer of information from hard copy to EDD. PM shall:

- Audit the transfer of information from hard copy to EDD to ensure the integrity of the electronic data. This should be done for each USTUR sample batch.
- Ensure that the records are maintained until termination of the USTUR contract.

2.15.4. Electronic Data

Electronic data shall be managed in such a way as to ensure and/or include:

Electronic data storage media are identified and indexed. These processes shall be included in laboratory SOPs.

The individuals responsible for entering and recording information on USTUR Sample Dissolution Log are uniquely identified when the information is recorded, and the times and dates of entry are documented.

Procedures and practices for verification of the accuracy of data are documented and included in SOPs.

2.15.5. Instrument Software Associated Total a-Counting

Software shall be managed in such as way as to ensure and/or include:

Approved SOPs exist for:

Verification and validation procedures to determine that all software programs accurately perform the intended functions. When indicated change-control procedures shall include reporting and evaluating problems and implementing corrective actions:

- Version control procedures that document the software version currently used and its implementation date.
- Maintaining a historical file of software including dates of use, software operating procedures (manuals), software changes, and software version numbers.

Documentation for the issues in section above is maintained. Laboratory management shall ensure that all documentation is readily available in the facility where the software is used.

2.15.6. Security

Laboratory management shall ensure that the security practices to ensure the integrity of electronic information:

- Ensure that calculation routines for total a-activity measurements are secure from inadvertent changes.
- Make login password necessary to access stored data, enter new data or change existing data.
- Establish access categories (read only, read/write, read/wrote/change) as appropriate to the duties of staff members.

2.15.7. Hardware

Laboratory management shall ensure that hardware and communications components are of adequate design and capacity, and that a written description is maintained.

Installed and operated in accordance with manufacturer's recommendations and, at installation, undergo acceptance testing.

Adequately inspected and maintained on an ongoing basis. Non-routine maintenance shall be documented, including a description of the problem, the corrective action, and the acceptance testing performed to ensure that the hardware or communications components have been properly repaired.

2.15.8. Records Retention

The contractor shall ensure that SOPs for records retention are implemented and that the staff follows the SOP specifications.

2.15.9. Facilities

With regard to facilities, contractor shall ensure that:

- The environmental conditions of the facility housing the hardware are appropriately regulated to protect against data loss.
- Environmentally adequate storage capacity is provided for retention of electronic data, storage media, and records pertaining to the computer systems.

2.15.10. Standard Operating Procedures for Total a-Counting

Contractor management shall ensure that:

- Each current SOP is readily available where the procedure is performed.
- SOPs are periodically reviewed at a frequency adequate to ensure that they accurately describe the current procedures.
- SOPs are approved and changed in accordance with contractor policy.
- A historical file of SOPs is maintained.

2.15.11. Records for Demonstration of Proficiency

The laboratory procedures must specify the records needed to document the initial demonstration of proficiency. A system for tracking and retrieving these records must be in place.

CHAPTER 3: DRYING/DISSOLUTION AND MEASUREMENT REQUIREMENTS

A critical step in the analytical scheme is the preparation and dissolution of the tissues and bones prior to separation of the nuclide(s) of interest and subsequent measurement(s).

To obtain the maximum scientific benefit from each analysis, the USTUR requires particular steps in the performance of the tissue and bone preparation prior to acid dissolution.

3.1. Sample Drying/Dissolution Requirements

3.1.1. General

Each ashing vessel (usually a borosilicate glass beaker) shall be covered with a watchglass during the any dry ashing cycle.

3.1.2. Bone samples

Drying step is applicable only for bone samples specified by USTUR.

The bones shall be unpacked from vacuum package, weighed and then dried overnight at 110°C, cooled to room temperature and weighed. The weight shall be recorded for future reporting to USTUR. Initially any bone sample shall be dried again overnight at 110°C, cooled to room temperature and weighed. These steps shall be repeated until essentially a constant dry weight is obtained prior to dry ashing at an elevated temperature, i.e., a maximum 1% change in sample weight. –Documentation of the bone dry weight should include the dates and masses of two last sample weight measurements.

Once the number of drying cycles has been established for each bone specimen type, the contractor's SOP will then include this requirement for each bone type.

3.1.3. Soft tissue samples

Most of the occupational exposures occur via inhalation but some wound cases exist as well. Some the lungs and lymph nodes of inhalation intakes will contain major amounts of the nuclide(s) of interest, thus cross-contamination of lower activity tissues is a concern. This will also be the case for a wound site and adjacent tissues.

3.1.4. Blanks

To test for the possibility of cross-contamination during drying ashing, the USTUR requires that certain tissue samples (to be identified by the USTUR) be dry ashed as described below.

Each lung, lymph nodes, wound site sample is to be placed in a muffle furnace with no other tissue or bone sample. The remainder of the available muffle furnace space shall be occupied with empty covered ashing vessels. These empty vessels shall then be handled in the same manner as the actual tissue including cycles of acid addition and dry ashing.

The “muffle blanks” will be analyzed along with the tissue to document any possible effect of dry ashing on sample batches. To aid in demonstrating the validity of placing several samples in a muffle furnace, the placement of the lung or lymph node or wound tissue should be varied relative to the “muffle blanks” vessels.

3.1.5. Final solution

After sample preparation and acid dissolution to a clear solution, the tissue or bone solution shall be converted to 6M HCl for delivery to the USTUR.

3.1.6. Worksheet Requirements

Contractor dissolution worksheets (bench-level) used to record reagents quantities shall present a complete record of all information pertinent to the dissolution of USTUR samples. A completed worksheet that includes the information listed below is required for each sample dissolution. The worksheets forms are computer generated and information is usually hand written using indelible ink.

- The name of the person who performed the analysis.
- The name or initials of the PM reviewer. (See Section 2.4.1 of this SOW for specific review requirements.)
- The SOP numbers.
- The date and time the dissolution was performed.

3.1.7. Techniques and SOPs

The contract laboratory shall employ approved techniques and SOPs in the dissolution of USTUR samples. If a nonstandard technique is required to achieve a specific USTUR objective, the contract laboratory will be asked to provide a schedule of charges of the work on a sample-by-sample basis.

3.2 Instrument Calibration Requirements

3.2.1. Analytical Instruments Calibration

Analytical instrument (balance etc.) calibration shall be performed only with NIST traceable standards. Instruments shall be calibrated at the contractor laboratory schedule.

3.2.2. Counting Instruments Calibration

Instruments used to acquire radiometric data shall be calibrated at the contractor laboratory schedule. Primary calibration for total a-activity measurements of filtered material shall be performed using NIST traceable standards except where such standards are unavailable. The words “check” and “verification” below apply to measurements performed to verify the primary calibrations. Standards used for this purpose shall be independent of the primary calibrants, and shall also be NIST traceable or have been directly compared with NIST standards. If such verifications fail, the laboratory shall reassess all data acquired since the last successful check and notify USTUR if corrections are made.

CHAPTER 4: DELIVERABLES REQUIREMENT

4.1 Dissolution Data Package Format and Contents

USTUR Sample Dissolution Log is a primary report form in both EDD and hard copy forms. A hard copy of the cover letter and comprehensive batch narrative are required for all reports submitted.

A batch narrative that describes the contents of the package and provides an index of samples associated with the delivery order (including both USTUR sample IDs and the contract laboratory sample IDs). A description of problems encountered in sample receipt, login, and dissolution shall also be included in the narrative. The batch narrative shall describe the circumstances involving UC and list the affected samples. All batch narratives shall include a signed statement affirming that the dissolution work and reporting package have been reviewed and are in compliance with the requirements of this SOW.

Signed and dated original COC forms received with each sample shipment, indicating sample receipt and custody by the contract laboratory.

Batch reports shall include all information necessary to support defensibility of the dissolution process.

Raw data shall include all information called for USTUR Sample Dissolution Log (Appendix A).

Standards certificate of analysis information, log entries for water quality, log entries for balance calibration verification, and other similar ancillary information shall not be included in analytical reports. The contract laboratory shall maintain such information as records.

The batch deliverable shall be placed on a CD-ROM and/or in .pdf. format and delivered to USTUR electronically as well as a hard copy.

4.2 Reporting Form for Total a-activity Measurement Results

The contractor reporting form shall comply with the following:

The contract laboratory shall specify USTUR sample ID, date of measurement, measurement system identification and report date.

For each total a-activity measurement, the contract laboratory shall provide the a-activity in Bq per filter, uncertainty value (1 sigma Poisson).

All results shall be reported in scientific notation (*e.g. 2*.05 E-03).

4.3 Deliverables Terms and Conditions

4.3.1. Turn-Around Times

A dissolution report is due to USTUR 30 calendar days from the date of receipt of each batch. Batch dissolution turn-around times are categorized as routine, rush, and emergency processing. Turn-around times for accelerated delivery requests shall be five calendar days for emergency and ten calendar days for rush dissolutions, with no holding time and shall be mutually agreed upon by the contract laboratory and USTUR. Batch reports with accelerated turn-around times shall be faxed, sent as .pdf format files or as email to USTUR, with the full deliverable due within the accelerated turn-around time.

Invoices shall be submitted monthly for the sample batches dissolved in that period. Invoices shall contain the number of samples per batch; dissolution performed, unit cost, and extended cost. Invoices shall be itemized and organized in such a way as to facilitate detailed review and cost verification without additional laboratory input.

4.3.2. Deliverable Deadlines

All electronic and hard copy deliverables for routine sample dissolutions are due 30 days after sample receipt. When an accelerated turn around time is requested, the deadlines specified Section 4.3.1 shall apply.

4.3.3. Price Reduction

All deliverables shall be due at the specified time unless express permission to deviate from the deliverable schedule is given by USTUR. Price reduction may be imposed for late deliverables at the discretion of the USTUR, depending on the contributing circumstances, at the rate of two percent per working day.

Unit prices will be those for the period when the deliverable arrives. However, the percent price reductions will be calculated based upon the originally requested turn around time. That is, a report for results with a ten-day requested turn around that arrives on the 15th day will be paid for at the 15-day turn around rates less ten percent.

Price reductions will not accumulate on weekends or holidays recognized by USTUR.

Price reductions will be applied to particular dissolutions when the quality is reduced by failure to comply with the requirements of the SOW for those dissolutions. Lost samples or inadequate dissolutions will not be paid for.

4.4 Program Documentation

Contract laboratory will provide the USTUR with a controlled copy of all program documentation such as procedures, quality manual, technical basis, etc initially and revision updates thereafter.

ACRONYMS

CAR Corrective Action Reports

COC Chain-of-Custody

CTR Contract Technical Representative

DQO Data Quality Objectives

GALP Good Automated Laboratory Practices

EDD Electronic Data Deliverable

PM Program Manager

QR Quarterly Report

SOW Statement of Work

UOC Unusual Occurrences

Appendix A - USTUR Sample Dissolution Log

USTUR Specifications					Contractor Report													
						Bone Sample Dry Weight, g		Reagent Used, g					GFPC (If Applicable)					Re
Sample No.	Organ or Tissue	Wet Sample Weight, g	Batch #	Date to Contractor	Received by	#1	#2	HNO3	HCl	H2O2	HF	H3BO3	# of filters	Activity, Bq	Ash Weight, g	6M HCl Solution Weight, g	Reported Date	
Blank #1	Reagent Blank															250		
Blank #2	Reagent Blank															250		