

5 OBTAINING LABORATORY SERVICES

5.1 Introduction

This chapter provides guidance on obtaining radioanalytical laboratory services. In particular, this chapter discusses the broad items that should be considered in the development of a procurement for laboratory services. Throughout this chapter, MARLAP uses the request for proposal (RFP) as an example of a procurement mechanism. Agencies and other organizations may use a variety of procurement mechanisms, depending upon circumstances and policies. The RFP typically includes a statement of work (SOW), generic contract requirements, and the description of the laboratory qualification and selection process. It should be noted that for some agencies or organizations, not all technical, quality, and administrative aspects of a contract are specified in a SOW; many are in the procurement document (RFP) or resulting contract. More detailed guidance and discussion on the content of the SOW and other contracting issues can be found in Appendix E (*Contracting Laboratory Services*). Appendix E includes types of procurement mechanisms (with emphasis on the request for proposal), typical proposal requirements, proposal evaluation and scoring, pre-award proficiency samples and audits, and post-award contract management. This chapter is written for contracting outside laboratory services, but the principal items and information provided would apply equally to similar services not requiring a formal contract, such as a service agreement within an Agency or organization. It should be noted that the information and specifications of a SOW may appear in many procurement documents other than a contract resulting from a RFP. These include purchase and work orders, task orders under existing Basic ordering agreements, or Government-wide Acquisition Contracts and Multiple Acquisition Schedule contracts, such as those offered by the U.S. General Services Administration. MARLAP recommends that technical specifications be prepared in writing in a single document, designated a SOW, for all radioanalytical laboratory services, regardless of whether the services are to be contracted out or performed by an Agency's laboratory.

Analytical protocol specifications (APSs) should be compiled in the SOW in order for the laboratory to propose the analytical protocols that the laboratory wishes to use for the project (Chapter 6). The development of APSs, which includes the measurement quality objectives (MQOs), is described in detail in Chapter 3, and the incorporation of these protocols into the relevant project plan documents is covered in Chapter 4. These specifications should include such items as the MQOs, the type and frequency of quality control (QC) samples, the level of performance demonstration needed, number and type of samples, turnaround times, and type of data package.

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Section 5.3 discusses the technical requirements of a SOW, Section 5.4 provides guidance on generic contractual requirements, and Section 5.5 discusses various elements of the laboratory selection and qualification criteria.

5.2 Importance of Writing a Technical and Contractual Specification Document

One objective of the SOW and contract documents is to provide the analytical requirements in a concise format that will facilitate the laboratory's selection of the appropriate analytical protocols. The authors of the SOW may be able to extract most, if not all, of the necessary technical information from properly prepared project plan documents (Chapter 4). If specific information is not available, the author should contact the planning team. The preparation of a SOW can be viewed as a check to make sure that the project planning documents contain all the information required for the selection and implementation of the appropriate analytical protocols. One important aspect of writing the SOW is that it should clearly identify the project laboratory's responsibility for documentation to be provided for subsequent data verification, validation, and quality assessment. These project laboratory requirements should be addressed in the assessment plans developed during directed planning (Chapter 2).

5.3 Statement of Work—Technical Requirements

A review of the project plan documents (Chapter 4) should result in a summary list of the technical requirements needed to develop a SOW. Much of this information, including the project MQOs and any unique analytical process requirements, will be contained in the APSs. When possible, a project summary of sufficient detail (i.e., process knowledge) to be useful to the laboratory should be included in the SOW. The project planning team is responsible for identifying and resolving key analytical planning issues and for ensuring that the resolutions of these issues are captured in the APSs. Consistent with a performance-based approach, the level of specificity in the APSs is limited to those requirements that are essential to meeting the project's analytical data requirements. In response to such project management decisions, the laboratory may propose for consideration several alternative validated methods that meet the MQOs under the performance-based approach (such as measurement of a decay progeny as an alternate radionuclide; see Section 6.6, "Method Validation"). Chapter 7 provides guidance on the evaluation of a laboratory and analytical methods.

The SOW should specify what the laboratory needs to provide in order to demonstrate its ability to meet the technical specifications in the RFP. This should include documentation relative to the method validation process to demonstrate compliance with the MQOs and information on previous contracts for similar analytical work as well as performance in performance evaluation (PE) programs using the proposed method. Any specific requirements on sample delivery

(Section 5.3.7) should also be made clear to the laboratory. In addition, the requirements for the laboratory's quality system should be discussed.

5.3.1 Analytes

Each APS should state the analyte of concern. The SOW should specify all analytes of concern and, when possible, an analyte's expected chemical form and anticipated concentration range (useful information for separating high activity samples from low activity samples) and potential chemical or radiometric interferences (Sections 3.3.1, "Develop Analyte List," and 3.3.2, "Identify Concentration Ranges"). In some instances, because of process knowledge and information on the absence of equilibrium between analytes and their parents and progeny, the SOW may require the direct measurement of an analyte rather than allowing for the measurement of other radionuclides in the analyte's decay chain. In these cases, the SOW should indicate the analyses to be performed. Examples of analyses include gross alpha and beta, gamma spectrometry, and radionuclide/matrix-specific combinations such as ^3H in water and ^{238}Pu in soil.

5.3.2 Matrix

Each APS should state the sample matrix to be analyzed. The sample matrix for each radionuclide or analysis type (e.g., gamma-ray spectrometry) should be listed and described in detail where necessary. The matrix categories may include surface soil, sub-surface soil, sediment, sludge, concrete, surface water, ground water, salt water, aquatic and terrestrial biota, air, air sample filters, building materials, etc. Additional information should be provided for certain matrices (e.g., the chemical form of the matrix for solid matrices) in order for the laboratory to select the appropriate sample preparation or dissolution method (Section 3.3.3, "Identify and Characterize Matrices of Concern").

5.3.3 Measurement Quality Objectives

The APSs should provide the MQOs for each analyte-matrix combination. The MQOs can be viewed as the analytical portion of the overall project data quality objectives (DQOs). An MQO is a statement of a performance objective or requirement for a particular method performance characteristic. Examples of method performance characteristics include the method's uncertainty at some concentration, detection capability, quantification capability, specificity, analyte concentration range, and ruggedness. An example MQO for the method uncertainty at some analyte concentration such as the action level would be, "A method uncertainty of 0.5 Bq/g or less is required at the action level of 5.0 Bq/g" (Chapters 1, 3, and 19). The MQOs are a key part of a project's APSs. Chapter 3 provides guidance on developing MQOs for select method performance characteristics.

5.3.4 Unique Analytical Process Requirements

The APS should state any unique analytical processing requirement. The SOW should give any matrix-specific details necessary for the laboratory to process the sample, such as type of soil, type of debris to be removed, whether or not filtering a sample at the laboratory is required, processing whole fish versus edible parts, drying of soils, information on any known or suspected interferences, hazards associated with the sample, etc. (see Section 3.4, “Matrix-Specific Analytical Planning Issues”). In some cases, unique analytical process requirements or instructions should be specified that further delineate actions to be taken in case problems occur during sample processing. For example, the SOW may require that the laboratory reprocess another aliquant of the sample by a more robust technique when a chemical yield drops below a stated value.

If necessary, special instructions should be provided as to how or when the analytical results are to be corrected for radioactive decay or ingrowth. In some cases, the sample collection date may not be the appropriate date to use in the decay or ingrowth equations.

5.3.5 Quality Control Samples and Participation in External Performance Evaluation Programs

The SOW should state the type and frequency of internal QC samples needed as well as whether they are to be included on a batch or some other basis (see Chapter 18, *Laboratory Quality Control*). The batch size may be defined in the SOW and may vary depending on the analysis type. The quality acceptance limits for all types of QC samples should be stated (see Appendix C for guidance on developing acceptance limits for QC samples based on the MQO for method uncertainty). In addition, the SOW should state when and how the project manager or the contracting officer’s representative should be notified about any nonconformity. In addition, the SOW should spell out the conditions under which the laboratory will have to reanalyze samples due to a nonconformance.

The evaluation of the laboratory's ability to perform the required radiochemical analyses should be based on the acceptability of the method validation documentation submitted by the laboratory. The evaluation should also include the laboratory’s performance in various external PE programs administered by government agencies or commercial radioactive source suppliers that are traceable to a national standards laboratory or organization, such as the National Institute of Standards and Technology (NIST). The source supplier’s measurement capabilities and manufacturing processes should be linked to NIST according to ANSI N42.22 (additional information on evaluating a laboratory’s performance is provided in Chapter 7). As such, the RFP should request the laboratory’s participation in a PE program, traceable to a national standards organization, appropriate for the analytes and matrices under consideration. In addition, the weighting factor (Appendix C) given to scoring the laboratory’s performance in such a program should be provided to the laboratory. Some examples of government programs include

DOE's Quality Assessment Program (QAP) and the Mixed Analyte Performance Evaluation Program (MAPEP) and the NIST-administered National Voluntary Laboratory Accreditation Program (NVLAP) Performance Testing (PT) providers.

5.3.6 Laboratory Radiological Holding and Turnaround Times

The SOW should include specifications on the required laboratory radiological holding time (i.e., the time between the date of sample collection and the date of analysis) and the sample processing turnaround time (i.e., the time between the receipt of the sample at the laboratory to the reporting of the analytical results). Such radiological holding and turnaround times, which are usually determined by specific project requirements, are typically specified in terms of calendar or working days. The SOW should state whether the laboratory may be requested to handle expedited or rush samples. In some cases, time constraints become an important aspect of sample processing (e.g., in the case of radionuclides that have short half-lives). Some analyses will call for specific steps that take a prescribed amount of time. Requesting an analytical protocol that requires several days to complete is obviously not compatible with a 24-hour turnaround time. This highlights the need for input from radioanalytical specialists during the planning process.

In some cases, the required sample-processing turnaround times are categorized according to generic headings such as routine, expedited or rush, and emergency sample processing. Under these circumstances, the SOW should specify the appropriate category for the samples and analyses.

5.3.7 Number of Samples and Schedule

Estimating the volume of work for a laboratory is commonly considered part of the planning process that precedes the initiation of a project. Thus, the SOW should estimate the anticipated amount of work and should spell out the conditions under which the laboratory will have to reanalyze samples due to some non-conformance. Similarly, the estimate should allow the laboratory to judge if its facility has the capacity to compete for the work. The estimate for the number of samples is a starting point, and some revision to the volume of work may occur, unless the laboratory sets specific limits on the number of samples to be processed.

The SOW should indicate whether samples will be provided on a regular basis, seasonally, or on some other known or unknown schedule. It should also be specified if some samples may be sent by overnight carrier for immediate analysis. Holidays may be listed when samples will not be sent to the laboratory. The SOW should state if Saturday deliveries may be required. Furthermore, it should specify whether samples will be sent in batches or individually, and from one location or different locations.

The carrier used to ship samples to the laboratory should be experienced in the delivery of field samples, provide next day and Saturday deliveries, have a package tracking system and be familiar with hazardous materials shipping regulations.

5.3.8 Quality System

The RFP should require that a copy of the laboratory's Quality System documentation (such as a Quality Manual), related standard operating procedures (including appropriate methods) and documentation (such as a summary of the internal QC and external PE sample results) be included with the proposal, as necessary. Only those radioanalytical laboratories that adhere to a well-defined quality system can ensure the appropriate quality of scientifically valid and defensible data. The laboratory's Quality System (NELAC, 2002; ANSI N42.23; ISO/IEC 17025) for a radioanalytical laboratory should address at a minimum the following items:

- Organization and management;
- Quality system establishment, audits, essential quality controls and evaluation and data verification;
- Personnel (qualifications and resumes);
- Physical facilities—accommodations and environment;
- Equipment and reference materials;
- Measurement traceability and calibration;
- Test methods and standard operating procedures (methods);
- Sample handling, sample acceptance policy and sample receipt;
- Records;
- Subcontracting analytical samples;
- Outside support services and supplies; and
- Complaints.

The Intergovernmental Data Quality Task Force (IDQTF) has developed a *Uniform Federal Policy for Implementing Environmental Quality Systems*. Agencies participating in the IDQTF are the Environmental Protection Agency, Department of Defense, and Department of Energy. The *Uniform Federal Policy* is a consensus document prepared by the IDQTF work group and it provides recommendations and guidelines for documentation and implementation of acceptable quality systems for federal agencies. Information on IDQTF and this policy may be found at www.epa.gov/swerffrr/documents/data_quality/ufp_sep00_intro.htm#quality.

5.3.9 Laboratory's Proposed Methods

Under the performance-based approach to method selection, the laboratory will select and identify radioanalytical methods (Chapter 6) that will meet the MQOs and other performance specifications of the SOW. MARLAP recommends that the laboratory submit the proposed methods and required method validation documentation with the formal response. The SOW

should state that the proposed methods and method validation documentation will be evaluated in accordance with established procedures by a technical evaluation committee (TEC) based on experience, expertise, and professional judgement. MARLAP uses the term TEC for the group that performs this function. Agencies and other organizations may use various terms and procedures for this process.

The TEC should provide their findings and recommendations to the organization's contracting officer for further disposition. In some cases, the organization may inform a laboratory that the proposed methods were deemed inadequate, and, if appropriate, request that the laboratory submit alternative methods with method validation documentation within a certain time period.

When the methods proposed by the laboratories have been deemed adequate to meet the technical specifications of the SOW, the TEC may want to rank the proposed methods (and laboratories) according to various factors (e.g., robustness, performance in PE programs or qualifying samples, etc.) as part of the contract scoring process.

5.4 Request for Proposal—Generic Contractual Requirements

Not all quality and administration aspects of a contract are specified in a SOW. Many quality (e.g., requirement for a quality system), administrative, legal, and regulatory items need to be specified in a RFP and eventually in the contract. Although not inclusive, the items or categories discussed in the following sections should be considered as part of the contractual requirements and specifications of a RFP.

5.4.1 Sample Management

The RFP should require the laboratory to have an appropriate sample management program that includes those administrative and quality assurance aspects covering sample receipt, control, storage and disposition. The RFP should require the laboratory to have adequate facilities, procedures, and personnel in place for the following actions (see Chapter 11, *Sample Receipt, Inspection, and Tracking*; and Chapter 17, *Waste Management in a Radioanalytical Laboratory*):

- Receive, log-in, and store samples in a proper fashion to prevent deterioration, cross-contamination, and analyte losses;
- Verify the receipt of each sample shipment: compare shipping documentation with samples actually received; notify the point of contact or designee by telephone within a prescribed number of business days and subsequently provide details in all case narratives of any discrepancies in the documentation;

- Sign, upon receipt of the samples, the sample receipt form or, if required, chain of custody (COC) form(s) submitted with each sample release. Only authorized laboratory personnel should sign the forms. The signature date on the COC form, if required, is normally the official sample receipt date. All sample containers should be sealed prior to their removal from the site; and
- Store unused portions of samples in such a manner that the analyses could be repeated or new analyses requested, if required, for a certain specified time period following the submission of an acceptable data package. Unused sample portions should be stored with the same sample handling requirements that apply to samples awaiting analysis. Documentation should be maintained pertaining to storage conditions and sample archival or disposal.
- Treat, store, or dispose of sample processing wastes, test and calibration sources, and samples (see also Section E.4.4.5, “Sample Storage and Disposal,” and Chapter 17)

5.4.2 Licenses, Permits and Environmental Regulations

Various federal, state, and local permits, licences and certificates (accreditation) may be necessary for the operation of a radioanalytical laboratory. The RFP should require the laboratory to have the necessary government permits, licenses, and certificates in place before the commencement of any laboratory work for an awarded contract. The following sections provide a partial list of those provisions that may be necessary. Some projects may require special government permits in order to conduct the work and transport and analyze related samples. For these cases, the necessary regulations or permits should be cited in the RFP.

5.4.2.1 Licenses

When required, the laboratory will be responsible for maintaining a relevant Nuclear Regulatory Commission (NRC) or Agreement State License to accept low-level radioactive samples for analyses. In certain circumstances, the laboratory may have to meet host nation requirements if operating outside the United States (e.g., military fixed or deployed laboratories located overseas).

When necessary, the laboratory should submit a current copy of the laboratory’s radioactive materials license with their proposal. Some circumstances may require a copy of the original radioactive materials license. For more complete information on license requirements, refer to either the NRC or state government offices in which the laboratory resides, or to 10 CFR 30.

5.4.2.2 Environmental and Transportation Regulations

Performance under a contract or subcontract must be in compliance with all applicable local, state, federal, and international laws and regulations. Such consideration must not only include

relevant laws and regulations currently in effect, but also revisions thereto or public notice that has been given that may reasonably be anticipated to be effective during the term of the contract.

The laboratory may be required to receive (and in some cases ship) samples according to international, federal, state, and local regulations (see Section 10.2.10, “Packaging and Shipping,” for details). In particular, the laboratory should be aware of U.S. Postal Service and Department of Transportation (DOT) hazardous materials regulations applicable to the requirements specified in the SOW and that appropriate personnel should be trained in these regulations. International shipping also is subject to International Air Transport Association Dangerous Goods Regulations.

5.4.3 Data Reporting and Communications

The type of information, schedules and data reports required to be delivered by the laboratory, as well as the expected communications between the appropriate staff or organizations, should be delineated in the RFP. The required schedule and content of the various reports, including sample receipt acknowledgment, chain of custody, final data results, data packages, QA/QC project summaries, status reports, sample disposition, and invoices should be provided in the RFP. In addition, the expected frequency and lines of communications should be specified.

In some cases, the RFP may request relevant information relative to the point-of-contact for certain key laboratory positions such as the Laboratory Director, Project Manager, QA Officer, Sample Manager, Record Keeping Supervisor, Radiation Safety or Safety Officer and Contracting Officer. Contact persons should be identified along with appropriate telephone numbers (office, FAX, pager), e-mail, and postal and courier addresses.

5.4.3.1 Data Deliverables

The SOW should specify what data are required for data verification, validation, and quality assessment. A data package, the pages of which should be sequentially numbered, may include a project narrative, the results in a specified format including units, a data review checklist, any non-conformance memos resulting from the work, sample receipt acknowledgment or chain of custody form (if required), sample and quality control sample data, calibration verification data, and standard and tracer information. In addition, the date and time of analysis, instrument identification, and analyst performing the analysis should be included on the appropriate paperwork. At the inception of the project, initial calibration data may be required for the detectors used for the work. When a detector is recalibrated, or a new detector is placed in service, updated calibration data should be required whenever those changes could affect the analyses in question. In some cases, only the summary or final data report may be requested. In these cases, the name of the data reviewer, the sample identification information, reference and analysis dates, and the analytical results along with the reported measurement uncertainties should be reported.

The SOW should specify the acceptable formats for electronic and hard copy records. The SOW also should state at what intervals the data will be delivered (batch, monthly, etc.).

5.4.3.2 Software Verification and Control

The policy for computer software verification, validation and documentation typically are included in the laboratory's Quality Manual. If there are specific software verification and validation requirements germane to the project, the RFP should instruct or specify such requirements. ASTM E919, "Standard Specification for Software Documentation for a Computerized System," describes computer program documentation that should be provided by a software supplier. Other sources for software QC are ANSI ANS 10.3 "Documentation of Computer Software" and IEEE Standard 1063, "IEEE Standard for Software User Documentation."

5.4.3.3 Problem Notification and Communication

Communication is key to the successful management and execution of the contract. Problems, schedule delays, potential overruns, etc., can be resolved quickly only if communication between the laboratory and organization's representative is conducted promptly. The RFP should state explicitly when, how, and in what time frame communication or notification is required by the laboratory for special technical events, such as the inability to meet MQO specifications for a sample or analyte, when a QC sample result is outside of an acceptance limit or some other non-conformance and when—if required by the project manager—the laboratory fails to meet its internal QC specifications.

The laboratory should document and report all deviations from the method and unexpected observations that may be of significance to the data reviewer or user. Such deviations should be documented in the narrative section of the data package produced by the contract laboratory. Each narrative should be monitored closely to assure that the laboratory is documenting departures from contract requirements or acceptable practice.

Communication from the organization's representative to the laboratory is also important. A key element in managing a contract is the timely review of the data packages provided by the laboratory. Early identification of problems allows for corrective actions to improve laboratory performance and, if necessary, the cessation of laboratory analyses until solutions can be instituted to prevent the production of large amounts of data that are unusable. Note that some sample matrices and processing methods can be problematic for even the best laboratories. Thus, the organization's technical representative must be able to discern between failures due to legitimate reasons and poor laboratory performance.

5.4.3.4 Status Reports

The SOW may require the laboratory to submit, on a specified frequency, sample processing status reports that include such information as the sample identification number, receipt date, analyses required, expected analytical completion date and report date. Depending on the project's needs, a status report may include the disposition of remaining portions of samples following sample processing or sample processing wastes.

5.4.4 Sample Re-Analysis Requirements

There may be circumstances when samples should be reanalyzed due to questionable analytical results or suspected poor quality as reflected by the laboratory's batch QC or external PT samples. Specific instructions and contractual language should be included in the RFP that address such circumstances and the resultant fiscal responsibilities (Appendix E).

5.4.5 Subcontracted Analyses

MARLAP recommends that the RFP state that subcontracting will be permitted only with the contracting organization's approval. In addition, contract language should be included giving the contracting organization the authority to approve proposed subcontract laboratories. For continuity or for quality assurance, the contract may require one laboratory to handle the entire analytical work load. However, the need may arise to subcontract work to another laboratory facility if the project calls for a large number of samples requiring quick turnaround times or specific methodologies that are not part of the primary laboratory's support services. The use of multiple service providers adds complexity to the organization's tasks of auditing, evaluating and tracking services.

Any intent to use a subcontracted laboratory should be specified in the response to the RFP or specific task orders. The primary laboratory should specify which laboratory(ies) are to be used, require that these laboratories comply with all contract or task order requirements, and verify that their operations can and will provide data quality meeting or exceeding the SOW requirements. Subcontract laboratories should be required to allow the contracting organization full access to inspect their operations, although it should be understood that the primary laboratory should maintain full responsibility for the performance of subcontract laboratories.

5.5 Laboratory Selection and Qualification Criteria

A description of the laboratory qualification and selection process should be stated in the RFP. The initial stages of the evaluation process focus on the technical considerations only. Cost will enter the selection process later. The organization's TEC considers all proposals and then makes an initial selection (see Figures E.6a and E.6b in Appendix E), at which time some laboratories

may be eliminated based on the screening process. The laboratory selection process is based on predetermined criteria that are related to the RFP and how a laboratory is technically able to support the contract. A laboratory that is obviously not equipped to perform work according to the RFP is certain to be dropped early in the selection process. In some cases, the stated ability to meet the analysis request may be verified by the organization, through pre-award audits and proficiency testing as described below. Letters notifying unsuccessful bidders may be sent at this time.

5.5.1 Technical Proposal Evaluation

The RFP requires each bidding contractor laboratory to submit a technical proposal and a copy of its Quality Manual. This Quality Manual is intended to address all of the technical and general laboratory requirements. As noted previously, the proposal and Quality Manual are reviewed by members of the TEC who are both familiar with the proposed project and are clearly knowledgeable in the field of radiochemistry and laboratory management.

5.5.1.1 Scoring and Evaluation Scheme

The RFP should include information concerning scoring of proposals or weighting factors for areas of evaluation. This helps a laboratory to understand the relative importance of specific sections in a proposal and how a proposal will be evaluated or scored. This allows the laboratory to focus on those areas of greater importance. If the laboratory submits a proposal that lacks sufficient information to demonstrate support in a specific area, the organization can then indicate how the proposal does not fulfill the need as stated in the request. Because evaluation formats differ from organization to organization, laboratories may wish to contact the organization for additional organization-specific details concerning this process. A technical evaluation sheet (TES) may be used in conjunction with the proposal evaluation plan as outlined in the next section (see Figures E.6a and E.6b in Appendix E) to list the total weight for each factor and to provide a space for the evaluator's assigned rating. In the event of a protest, the TES can be used to substantiate the selection process. The TES also provides areas to record the RFP number, identity of the proposer, and spaces for total score, remarks, and evaluator's signature. The scoring and evaluation scheme is based on additional, more detailed, considerations which are discussed briefly in the Sections E.4 and E.5 of Appendix E.

Once all proposals are accepted by the organization, the TEC scores the technical portion of the proposal. MARLAP recommends that all members of the TEC have a technical understanding of the subject matter related to the proposed work. These individuals are also responsible for responding to any challenge to the organization's selection for the award of the contract. Their answers to such challenges are based on technical merit in relation to the proposed work.

5.5.1.2 Scoring Elements

Although each organization may have a different scoring process to evaluate a laboratory's response to a RFP, there are various broad categories or common elements that are typically evaluated. For example, these may include the following:

- Technical merit;
- Adequacy and suitability of laboratory resources and equipment;
- Staff qualifications;
- Related experience and record of past performance; and
- Other RFP requirements.

Although each organization may score or weight these items differently, performance-based contracting requires the weighting of past performance of the contractor as a significant technical element. Each of these elements is considered in the following paragraphs. Outlined below are the key elements that are discussed in more detail in Appendix E.

TECHNICAL MERIT

The response to the RFP should include details of the laboratory's quality system and all the analytical methods to be employed by the laboratory as well as the method validation documentation (Section 6.6). The information provided should outline or demonstrate that the methods proposed are likely to be suitable and meet the APSs. The methods should be evaluated against the APSs and MQOs provided in the SOW. Chapter 7 provides guidance on the evaluation of methods and laboratories. The laboratory's Quality Manual should be reviewed for adequacy and completeness to ensure the required data quality.

ADEQUACY AND SUITABILITY OF LABORATORY RESOURCES AND EQUIPMENT

When requested, the laboratory will provide a listing of the available instrumentation or equipment by analytical method category. In addition, the RFP may request information on the available sample processing capacity and the workload for other clients during the proposed contract period. The information provided should be evaluated by the TEC to determine if the laboratory has the sample processing capacity to perform the work. The instrumentation and equipment must be purchased, set-up, calibrated, and on-line before award of contract. In addition, the laboratory should provide information relative to the adequacy and suitability of the laboratory space available for the analysis of samples.

STAFF QUALIFICATIONS

The RFP should require the identification of the technical staff and their duties, along with their educational background and experience in radiochemistry, radiometrology or laboratory

operations. The laboratory staff that will perform the radiochemical analyses should be employed and trained prior to the award of the contract. Appendix E provides guidance on staff qualifications.

RELATED EXPERIENCE AND RECORD OF PAST PERFORMANCE

The RFP should require the laboratory to furnish references in relation to its past or present work. To the extent possible, this should be done with regard to contracts or projects similar in composition, duration and number of samples to the proposed project. In some cases, the laboratory's previous performance for the same Agency may be given special consideration.

OTHER RFP REQUIREMENTS

Within the response to the RFP, the laboratory should outline the various programs and commitments (QA, safety, waste management, etc.) as well as submit various certifications, licences, and permits to ensure the requirements of the RFP will be met. The reasonableness of the proposed work schedule, program, and commitments should be evaluated by the TEC. In addition, if accreditation is required in the RFP, the TEC should confirm the laboratory's accreditation for radioanalytical services by contacting the organization that provided the certification. The National Environmental Laboratory Accreditation Conference (NELAC) is an organization formed to establish and promote performance standards for the inspection and operation of environmental laboratories in support of the National Environmental Laboratory Program (NELAP). States and federal agencies serve as the accrediting authorities within NELAP. If state-accredited, a laboratory typically is accredited by the state in which it resides, and if the state is a NELAP-recognized accrediting authority, the accreditation is recognized by other states and federal agencies approved under NELAP. If the state is not a NELAP-recognized accrediting authority, and an organization expects a laboratory to process samples from other states or the federal government, then additional accreditations may be required. The TEC should review and confirm the applicability and status of the licenses and permits with respect to the technical scope and duration of the project.

5.5.2 Pre-Award Proficiency Evaluation

Some organizations may elect to send proficiency or PT samples (sometimes referred to as "performance evaluation" or "PE" samples) to the laboratories that meet a certain scoring criteria in order to demonstrate the laboratory's analytical capability. The composition and number of samples should be determined by the nature of the proposed project. The PT sample matrix should be composed of well-characterized materials. It is recommended that site specific PT matrix samples or method validation reference material (MVRM; see Section 6.5.1, "Matrix and Analyte Identification") be used when available.

Each competing lab should receive an identical set of PT samples. The RFP should specify who will bear the cost of analyzing these samples as well as the scoring scheme (e.g., “pass/fail” or a sliding scale). Any laboratory failing to submit results should be disqualified. The results should be evaluated and each laboratory given a score. This allows the organization to make a second cut—after which only two or three candidate laboratories are considered.

5.5.3 Pre-Award Assessments and Audits

The RFP should indicate that the laboratories with the highest combined scores for technical proposals and proficiency samples may be given an on-site audit. A pre-award assessment or audit may be performed to provide assurance that a selected laboratory is capable of fulfilling the contract in accordance with the RFP. In other words, is the laboratory’s representation of itself accurate? To answer this question, auditors should be looking to see that a candidate laboratory appears to have all the required elements to meet the proposed contract’s needs. Refer to Appendix E for details on the pre-award assessments and audits.

5.6 Summary of Recommendations

- MARLAP recommends that technical specifications be prepared in writing in a single document, designated a SOW, for all radioanalytical laboratory services, regardless of whether the services are to be contracted out or performed by an Agency’s laboratory.
- MARLAP recommends that the MQOs and analytical process requirements contained in the SOW be provided to the laboratory.
- MARLAP recommends that the SOW include the specifications for the action level and the required method uncertainty for the analyte concentration at the action level for each analyte/matrix.
- MARLAP recommends that the laboratory submit the proposed methods and required method validation documentation with the formal response.
- MARLAP recommends that the RFP state that subcontracting will be permitted only with the contracting organization’s approval.
- MARLAP recommends that all members of the TEC have a technical understanding of the subject matter related to the proposed work.

5.7 References

5.7.1 Cited References

American National Standard Institute (ANSI) N42.23. *Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories*. 2003.

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