APPENDIX E
CONTRACTING LABORATORY SERVICES

E.1 Introduction

This appendix provides general guidance on federal contracting and contracting terminology as used for negotiated procurements. Federal agencies, and laboratories doing business with them, must follow applicable provisions of the *Federal Acquisition Regulations* (FAR) and agency-specific supplements. The examples provided in this appendix are based primarily on procedures followed by the U.S. Geological Survey (USGS).

This appendix addresses selecting a laboratory to establish services that supplement an agency's in-house activities through the contracting of additional outside support. This appendix offers a number of principles that may be used when selecting a service provider, establishing a contractual agreement, and later working with a contract laboratory. These principles may also be applied to contractors that are located outside of the United States. In such cases, legal counsel will need to review and advise an agency concerning pertinent issues related to international contracts.

This appendix also covers laboratory audits that are part of a final selection process and other activities that take place until the contract is concluded. Chapter 5 (*Obtaining Laboratory Services*) supports this appendix with a general description on how to obtain laboratory services. Chapter 7 (*Evaluating Methods and Laboratories*) complements this appendix by considering information related to laboratory evaluations that are conducted throughout the term of a project—whether or not this work is specifically covered by a contract.

Obtaining support for laboratory analyses is already a practice that is familiar to a number of federal and state agencies. The following discussion will apply:

- *Agency*: A federal or state government office or department, (or potentially any other public or private institution) that offers a solicitation or other mechanism to obtain outside services;
- *Proposer*: A person, firm, or commercial facility that submits a proposal related to providing services; and
- *Contractor*: A person or firm that is awarded the contract and is engaged in providing analytical services.

Contents

Furthermore, the size and complexity of some agency projects will clearly exceed the extent of the information presented here. In its present form, this appendix serves to touch on many of the issues and considerations that are common to all projects, be they large or small.

MARLAP draws attention to another dimension of the overall contracting process by considering how the data quality objectives (DQOs) and measurement quality objectives (MQOs) are incorporated into every stage of a project—as described earlier in greater detail (Chapters 2, *Project Planning Process*, and 3, *Key Analytical Planning Issues and Developing Analytical Protocol Specifications*). In this regard, an agency's project managers and staff are given an opportunity to consider options with some foresight and to examine the larger picture, which concerns planning short- or long-term projects that utilize a contractor's services. As services are acquired, and later as work is performed, the specific concepts and goals outlined by the DQOs and MQOs will be revisited. This becomes an iterative process that offers the possibility to further define objectives as work is conducted. Whenever the DQOs or MQOs are changed, the contract should be modified to reflect the new specifications. Employing the MQOs and tracking the contractor's progress provides a means by which project managers and contract-laboratory technical staff can return and review the project at any point during the contract period. This allows for repeated evaluations to further optimize a project's goals and, if anticipated in the contract's language, perhaps even provides for the option to revise or redirect the way performance-based work is conducted.

The Office of Federal Procurement Policy (OFPP, 1997) has developed a Performance-Based Service Contracting review checklist to be used as a guide in developing a performance-based solicitation. The checklist contains minimum required elements that should be present for a contract to be considered performance-based. Performance-Based Service Contracting focuses on three elements: a performance work statement; a quality assurance project plan (QAPP); and appropriate incentives, if applicable. The performance work statement defines the requirements in terms of the objective and measurable outputs. The performance work statement should answer five basic questions: what, when, where, how many, and how well. The work statement should structure and clearly define the requirements, performance standards, acceptable quality levels, methods of surveillance, incentives if applicable and evaluation criteria. A market survey should be conducted so that the marketplace and other stakeholders are provided the opportunity to comment on draft performance requirements and standards, the proposed QA project plan, and performance incentives, if applicable.

A number of benefits arise from establishing a formal working relationship between an agency and a contractor. For example:

- A contract is a legal document that clearly defines activities and expectations for the benefit of both parties engaged in the contractual relationship.

- The process of drafting language to cover legal considerations may well include contributions from legal staff. Legal guidance may be obtained as needed at any time during the planning stages or later when a contract is in place. However, the core of a contractor's proposal, and eventually the contract itself, provide the foundation of technical work that is required to complete a project or attain an ongoing program goal. *In this regard, aside from legal issues that are an integral part of every contract, this appendix's principal focus is on the laboratory process or technical work-related content of the contract*.

- The statement of work (SOW) first appears as part of the agency's request for proposal (RFP) and later is essentially incorporated into the proposal by the proposer when responding to the RFP. When work is underway, the SOW becomes a working document that both the agency and contractor refer to during the life of the contract.

- Legal challenges concerning project results (i.e., laboratory data) may arise during the contract period. The language in a contract should offer sufficient detail to provide the means to circumvent potential or anticipated problems. For example, attention to deliveries of samples to the laboratory on weekends and holidays or data reporting requirements that are designed to support the proper presentation of data in a legal proceeding are important aspects of many federal- and state-funded contracts.

Overall, this appendix incorporates a sequence that includes both a planning and a selection process. Figure E-1 illustrates a series of general steps from planning before a contract is even in place to the ultimate termination of the contract. An agency first determines a need as part of planning, and along the way advertises this need to solicit proposals from outside service providers who operate analytical laboratory facilities. Planning future work, advertising for, and later selecting services from proposals submitted to an agency takes time—perhaps six or more months pass before a laboratory is selected, a contract is in place, and analytical work begins. The total working duration of a contract, for example, might cover services for a brief time (weeks or months) and in other cases, many contracts may run for a preset one-year period or for a more extended period of three to five years with optional renewal periods during that time.

The MARLAP user will find that planning employs a thought process much like that used to prepare an RFP. In general, one starts with questions that define a project's needs. Further, by developing Analytical Protocol Specifications (APSs) which include specific MQOs, one enters an iterative process such that—at various times—data quality is checked in relation to work performed both in-house and by the outside service provider. Overall, planning results in the development of a project plan document (e.g., QAPP). During planning, a project manager and the agency staff can consider both routine and special analytical services that may be required to provide data of definable quality. The SOW serves to integrate all technical and quality aspects of the project, and to define how specific quality-assurance and quality-control activities are implemented during the time course of a contract. Also, at an early stage in planning, the agency may choose to assemble a team to serve as the Technical Evaluation Committee (TEC; Section

E.5.1). The main role of the TEC is in selecting the contract laboratory by reviewing proposals and by auditing laboratory facilities. The TEC is discussed later in this appendix, however, the key issue here concerns the benefit to establishing this committee early on, even to the point of including TEC members in the initial planning activities. The result is a better informed evaluation committee and a team of individuals that can help make adjustments when the directed planning process warrants an iterative evaluation of the way work is performed under the contract. Overall, planning initiates the process that characterizes the nature of the contracting process to follow.

E.2 Procurement of Services

Recognizing that the procurement process differs from agency to agency, the following guidance provides a general overview to highlight considerations that may already be part of—or be incorporated into—the current practice. First, the request for specific analytical services can be viewed as a key product of both the agency's mission and the directed planning process. As agency staff ask questions, list key considerations to address during the work, and in turn define objectives, they

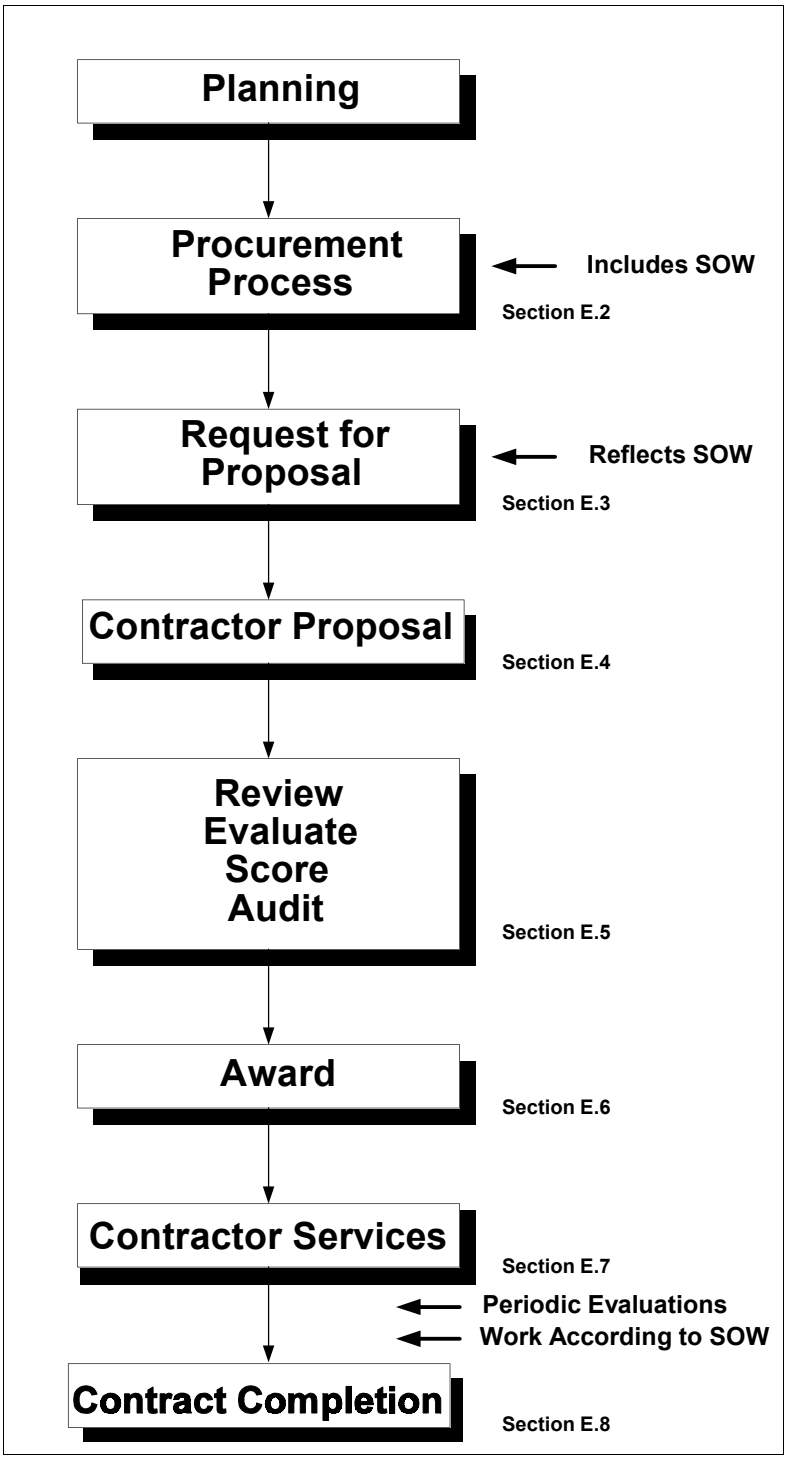

FIGURE E.1 — General sequence initiating and later conducting work with a contract laboratory

also eliminate unnecessary options to help focus on the most suitable contracting options that satisfy the APSs. Thereafter, the scope of the work, schedule, manpower constraints, availability of in-house engineering resources, and other technical considerations all enter into estimating and defining a need for project support. This approach refines the objectives and establishes needs that may be advertised in a solicitation for outside services. The resulting work or project plan should clearly articulate what is typically known but not limited to the following:

- Site conditions;
- Analytes of interest;
- Matrices of concern;
- How samples are to be collected and handled;
- Custody requirements;
- Data needs and APSs, including the MQOs;
- Stipulated analytical methods, if required;
- Applicable regulations; and
- Data reporting.

All of this defines the scope of work, such that the agency can initiate a formal request for proposals or arrange for an analysis request as part of a less formal procurement.

E.2.1 Request for Approval of Proposed Procurement Action

If required within an agency, a request is processed using forms and related paperwork to document information typically including, but not limited to, the following:

- Identification of product or service to be procured;
- Title of program or project;
- Description of product or service;
- Relationship of product or service to overall program or project;
- Funding year, projected contract life, amounts, etc.;
- Name and phone number of Project Officer(s);
- Signature of Project Officer and date
- Name and phone number of Contracting Officer; and
- Signature of Contracting Officer and date.

An agency may also be required to collect or track information for an RFP with regard to:

- New procurements: type of contract, grant, agreement, proposal, etc. Continuing procurements: pre-negotiated options, modifications, justification for noncompetitive procurement, etc.
- Source information: small business or other set aside, minority business, women-owned business, etc.

In addition to the information listed above, agency-specific forms used to initiate a procurement request may also provide a place to indicate agency approval with names, signature lines, and date spaces for completion by officials in the office responsible for procurement and contracts. An agency administrator or director above the level of the office of procurement may also sign this form indicating agency approval.

E.2.2 Types of Procurement Mechanisms

Table E.1 lists many of the procurement options available to the project manager. Each option offers a solution to a specific need. For example, a purchase order is typically appropriate for tasks with a somewhat limited scope and thus is perhaps most useful when samples are to be processed on a one-time basis. In some cases where only one or a limited number of vendors can fulfill the needs of the project, e.g., low-level tritium analysis by helium ingrowth within a specified time period, a sole source solicitation is commonly used.

TABLE E.1— Examples of procurement options to obtain materials or services

Procurement Mechanism	Example of Specific Use or Application
Purchase order	In-house process handled through purchasing staff; limited to small needs without a formal request or used in conjunction with a solicitation (competitive process) and a limited amount of funding; commonly used to purchase equipment and supplies, but may be used for processing samples.
Sole source solicitation	In specific instances, a single or a limited number of service providers are able to offer specific services.
Request for Quotation (RFQ)	Formal, main process for establishing contracts—generally addresses a major, long-term need for contractor support; this is a competitive process based mainly on cost.
Request for Proposal (RFP)	Formal, main process for establishing contracts—generally addresses a major, long-term need for contractor support; this is a competitive process based mainly on technical capability.
Modification to an existing contract or delivery order	This approach meets a need that is consistent with the type of contract that is in place, e.g., agency amends contract to add a method for sample processing that is similar to work already covered.
Basic Ordering Agreement (BOA)	Work is arranged with a pre-approved laboratory as described in Section E.2.2.

The process leading to a formal contract provides a more comprehensive view of nearly every aspect of the work that an agency expects from a contractor. The formal process includes three types of procurement: request for quotation (RFQ), request for proposal (RFP), and the basic ordering agreement (BOA). The RFQ solicits bidders to provide a quotation for laboratory services that have been detailed in the solicitation. The specifications may include the technical, administrative, and contractual requirements for a project. For the RFQ, the contract typically is

awarded to the lowest bidder that can fulfill the contract specifications without regard to the quality of the service. What appears to be a good price may not entail the use of the best or most appropriate method or technology. There may be significant advantages in seeking to acquire high-technology services as a primary focus in advance of, or along with, concerns pertaining to price.

For an RFP, there is considerably more work for the agency and the laboratory. The laboratory must submit a formal proposal addressing all key elements of the solicitation that include how, why, what, when, where and by whom the services are to be performed. The TEC or Contracting Officer must review all proposals, rank them according to a scoring system and finally assess the cost effectiveness of the proposals before making the final award.

The BOA provides a process that serves to pre-approved service providers. This includes a preliminary advertisement for a particular type of work, such as radioanalytical services. The agency then selects and approves a number of candidates that respond to the advertisement. With this approach, the agency assembles a potential list of approved laboratories that are contacted as needed to support specific needs. The agency may choose to simply write a task order (defining a specific scope of work) with a specific pre-approved laboratory, or the agency may initiate a competitive bidding process for the task order between several or all members on the list of pre-approved laboratories. Once chosen, the laboratory may be guided by a combined statement of work or task order that is issued by the agency.

Mechanisms that permit an agency to obtain analyses for a limited number of samples—without an established contractual relationship with a specific contractor—may simply be necessitated by the small number of samples, time constraints where specific analyses are not part of an existing contract, limitations related to funding, or other consideration. The formal business and legal requirements of a long-term relationship warrant a stronger contractual foundation for work conducted in a timely fashion, on larger numbers of samples, and over specified periods of time. The contracts described above, with the exception of a BOA, are considered "requirement" contracts and requires the group initiating the solicitation to use only the contracted laboratory, without exception, for the contract period to perform the sample analyses.

E.3 Request for Proposals—The Solicitation

To appreciate the full extent of a competitive process leading to a formal working relationship—between an agency and a contractor—*the primary example used hereafter is the solicitation and selection process that starts with the issuance of a* RFP, as shown in Figure E-1.

Federal announcements of RFPs can be found on the *Federal Business Opportunities* (FBO) web site (http://vsearch1.eps.gov/servlet/SearchServlet); many agencies also announce their own RFPs on their own web sites. FBO primarily provides a synopsis or brief description of the type

of work the agency is interested in purchasing. States and local governments also solicit proposals and announce the availability of work in USABID (a compilation of solicitations from hundreds of city, county, and state agencies). Internet sites that offer access to the FBO and USABID listings can be located through electronic searches using web browser software. Once a site is located, the information can be viewed through public access or commercial Internet-based services. In other cases, a state or federal agency may maintain a mailing list with names and addresses for potentially interested parties. This might include contractors that previously supported the Agency or others who have volunteered information for the mailing list.

Once the RFP, state advertisement, or other form of solicitation is publicized, interested parties can contact the appropriate Agency to obtain all the specific information relevant to completing a candidate laboratory's contract proposal. For the present discussion, this information is contained in the text of the RFP document. The RFP may be accompanied by a cover letter stating an invitation to applicants and general information related to the content of a proposal and specific indication for the types of sections or sub-sections the proposal will contain. For example, a proposal divided into three sections technical proposal, representations and certifications, and price proposal allows the agency to separate pricing from technical information. In this way, the agency considers each candidate first on technical merits before the price of services enters the selection process.

The agency's RFP is designed to provide a complete description of the proposed work. For example, a RFP should inform all candidate laboratories (i.e., proposers) of the estimated number of samples that are anticipated for processing under the contract. The description of work in the RFP as described in the SOW serves to indicate the types of radionuclide analyses required for the stated sample types and the number of samples to undergo similar or different processing protocols. The estimate also has a bearing on cost and other specific project details as described in the SOW. Additional information provided with the RFP serves to instruct the proposer regarding other technical requirements (APSs), the required number of copies of each section of the proposal, proposal deadline, address where proposals are to be sent, and other general concerns or specifications relevant to the solicitation.

The cover letter may indicate how each proposer will be notified if its proposal is dropped from the competitive range of candidates during the selection process. The letter may also include precautionary notes concerning whom to contact or not contact at the agency regarding the potential contract during the competitive process. Finally, if particular sources are encouraged to apply (e.g., minority or small business), this information will be mentioned in the agency's invitation to apply.

E.3.1 Market Research

The Office of Federal Procurement Policy (OFPP, 1997) recommends that the marketplace and other stakeholders be provided the opportunity to comment on draft performance requirements

and standards. This practice allows for feedback from those people working in the technical community so that their comments may be incorporated into the final RFP and potential proposers can develop intelligent proposals.

E.3.2 Period of Contract

The time and resources involved in writing and awarding a major contract generally make it impractical and cost ineffective to award contracts for less than one or more years. While contracts running for shorter terms are sometimes established, single or multiple year terms are commonly used to provide the necessary services for some federal or state programs. Monitoring programs are likely to go long periods of time with renewals or RFPs that continue the work into the future. Elsewhere, relatively large projects conducting radiation survey and site investigations may require a contract process that, for the most part, estimates the time services will be needed to finish work through to the completion of a final status survey. In this case, the contract may specify any length of time, but also include the option to renew the contract for a period of time to bring the project to a close. The relationship between the length of a contract and the type of project can be part of the structured planning process that seeks to anticipate every facet of a project from start to finish.

Multi-year contracts typically are initiated with an award for the first year or two followed by an additional number of one-year options. In this way, a five-year contract is awarded for one year (or two) with four (or three) one-year option periods to complete the contract's full term. The government must exercise its option for each period beyond the base term. Problems that arise during any year may result in an agency review of the MQOs or an examination of the current working relationship that may result in the agency's decision to not extend the contract into the next option year.

E.3.3 Subcontracts

For continuity or for quality assurance (QA), the contract may require one laboratory to handle the entire analytical work load. However, subcontracting work with the support of an additional laboratory facility may arise if the project plan calls for a large number of samples requiring quick turnaround times and specific methodologies that are not part of the primary laboratory's support services. A proposer may choose to list a number of subcontractors in the proposal. The listing may or may not include other laboratories with whom the proposer has an existing or prior working relationship. The choice of subcontracting firms may be limited during the proposal process. There may be many qualified service providers to meet specific project needs. However, once work is under way, using a limited number of laboratories that qualify for this secondary role helps maintain greater control of quality and thus the consistency of data coming from more than a single laboratory alone. Furthermore, the contractor may prefer working with a specific subcontractor, but this arrangement is subject to agency approval.

The use of multiple service providers adds complexity to the agency's tasks of auditing, evaluating, and tracking services. The prime contractor and their subcontractor(s) are held to the same terms and conditions of the contract. The prime contractor is responsible for the performance of its subcontract laboratories. In some instances, certain legal considerations related to chain of custody, data quality and reporting, or other concern may limit an agency's options and thus restrict the number of laboratories that are part of any one contract.

However, the decision to use an approved subcontractor, or which subcontractor to use, is strictly up to the prime. Under federal contracting regulations, agencies may not direct a laboratory to use a particular subcontractor, nor may the federal customer deal directly with the subcontractor (without going through the prime contractor). This may create a more convoluted or complex relationship among the customer, prime contractor, and subcontractors, which in turn may affect turnaround times and quality. Consequently, a laboratory's quality manual and proposal should address its approach for ensuring timely and accurate communications between the customer, prime contractor, and subcontractor(s).

E.4 Proposal Requirements

The agency's RFP will state requirements that each proposer is to cover in its proposal. The proposal document itself becomes first the object of evaluation and is a reflection of how the contract and the SOW are structured. Whether one works with a formal contract or a simpler analysis request, the agency and contractor need to agree to all factors concerning the specific analytical work. Where written agreements are established, the language should be specific to avoid disputes. Clear communication and complete documentation are critical to a project's success. For example, the agency's staff asks questions of itself during the planning process to create and later advertise a clearly stated need in the RFP. The contractor then composes a proposal that documents relevant details concerning their laboratory's administrative and technical personnel, training programs, instrumentation, previous project experience, etc. Overall, the proposer should make an effort to address every element presented in the RFP. The proposer should be as clear and complete as possible to ensure a fair and proper evaluation during the agency's selection process.

The planning process will reveal numerous factors related to technical requirements necessary to tailor a contract to specific project needs. The following sections may be reviewed by agency staff (radiochemist or TEC) during planning to determine if additional needs are required beyond those listed in this manual. agency personnel should consider carefully the need to include every necessary detail to make a concise RFP. The proposer can read the same sections to anticipate the types of issues that are likely to appear in an RFP and that may be addressed in a proposal.

E.4.1 RFP and Contract Information

There are two basic areas an agency can consider when assembling information to include in an RFP. The proposer is expected to respond with information for each area in its proposal. The first area includes a listing of *General Laboratory Requirements and Activities*. The second area, *Technical Components to Laboratory Functions*, complements the first, but typically includes more detailed information.

1) General laboratory requirements
- Personnel;
- Facilities;
- Meeting contract data quality requirements;
- Schedule;
- Quality manual;
- Data deliverables including electronic format;
- Licenses and certifications; and
- Experience: previous and current contracts; quality of performance.

2) Technical components to laboratory functions
- Standard operating procedures;
- Instrumentation
- Training
- Performance evaluation programs; and
- Quality system.

The laboratory requirements and technical components indicated above are addressed in this appendix. Beyond this, there are additional elements that may be required to appear with detailed descriptions in an RFP and later in a formal proposal. One significant portion of the RFP, and a key element appearing later in the contract itself, is the SOW. This is the third area a proposer is to address, and information in a SOW may vary depending on the nature of the work.

The agency will provide specifications in the RFP regarding the work the contractor will perform. This initiates an interaction between a proposer and the agency and further leads to two distinct areas of contractor-agency activity. The first concerns development and submitting of proposals stating how the laboratory work will be conducted to meet specific agency needs. The second concerns agency evaluations of the laboratory's work according to contract specifications (Section E.5) and the SOW. Once the contract is awarded, a contractor is bound to perform the work as proposed.

Specific sections of each contract cover exactly what is expected of the contractor and its analytical facilities to fulfill the terms and conditions of the contract. The SOW describes the required tasks and deliverables, and presents technical details regarding how tasks are to be

executed. A well written SOW provides technical information and guidance that directs the contractor to a practice that is technically qualified, meets all relevant regulatory requirements, and appropriately coordinates all work activities. A sample checklist for key information that may be in a SOW is presented in Table E.2. Note that not all topics in the list are appropriate for each project, and in some cases, only a subset is required. The list may also be considered in relation to less formal working relationships (e.g., purchase order), as well as tasks covered in formal contracts.

TABLE E.2 — SOW checklists for the agency and proposer

SAMPLE HISTORY
____ General background on the problem
____ Site conditions
____ Regulatory background
____ Sample origin
____ Analytes and interferences (chemical forms and estimated concentration range)
____ Safety issues
____ Data use
  ____ Regulatory compliance
  ____ Litigation

ANALYSIS RELATED
____ Number of samples
____ Matrix
____ Container type and volume
____ Receiving and storage requirements
____ Special handling considerations
____ Custody requirements
____ Preservation requirements, if any
____ Analytes of interest (specific isotopes or nuclide)
____ Measurement Quality Objectives
____ Proposed method (if appropriate) and method validation documentation
____ Regulatory reporting time requirement (if applicable)
____ Analysis time requirements (time issues related to half-lives)
____ QC requirements (frequency, type, and acceptance criteria)
____ Waste disposal issues during processing
____ Licenses and accreditation

OVERSIGHT
____ Quality manual
____ Required Performance Evaluation Program participation
____ Criteria for (blind) QC
____ Site visit/data assessment
____ Audit (if any)

REPORTING REQUIREMENTS
____ Report results as gross, isotopic....
____ Reporting units
____ Reporting basis (dry weight, ...)
____ How to report measurement uncertainties
____ Reporting Minimum Detectable Concentration and Minimum Quantifiable Concentration
____ Report contents desired and information for electronic data transfer
____ Turn-around time requirements
____ Electronic deliverables
____ Data report format and outline

TABLE E.2 — SOW checklists for the agency and proposer

NOTIFICATION
____ Exceeding predetermined Maximum Concentration Levels - when applicable
____ Batch QC failures or other issues
____ Failure to meet analysis or turnaround times
____ Violations related to radioactive material license
____ Change of primary staff associated with contract work
SCHEDULE
____ Expected date of delivery
____ Method of delivery of samples
____ Determine schedule (on batch basis)
____ Method to report and resolve anomalies and nonconformance in data to the client
____ Return of samples and disposition of waste
CONTACT
____ Name, address, phone number of responsible parties

E.4.2 Personnel

The education, working knowledge, and experience of the individuals that supervise operations, conduct analyses, operate laboratory instruments, process data, and create the deliverables is of key importance to the operation of a laboratory. The agency is essentially asking who is sufficiently qualified to meet the proposed project's needs. (The answer to this question may come from an agency's guidance or other specific requirements generated by the structured planning process.) The laboratory staff that will perform the analyses should be employed, trained, and qualified prior to the award of the contract.

In response to the RFP, the proposer should include a listing of staff members capable of managing, receiving, logging, preparing, and processing samples; providing reports in the format specified by the project; preparing data packages with documentation to support the results; maintaining the chain of custody; and other key work activities. The laboratory should list the administrative personnel and appoint a technical person to be a point of contact for the proposed work. This person should fully understand the project's requirements and be reasonably available to respond to every project need. A proposal should include the educational background and a brief resume for all key personnel. The level of training for each technician should be included.

Tables E.3 and E.4 are examples that briefly summarize the suggested minimum experience, education, and training for the listed positions. Note, some agency-specific requirements may exceed the suggested qualifications and this issue should be explored further during the planning process. The goal is to provide basic guidance with examples that the MARLAP user can employ as a starting point during planning. Once specific requirements are established, this information will appear in the RFP. Table E.3 provides a listing for the types of laboratory technical supervisory personnel that are likely to manage every aspect of a laboratory's work. Each position title is given a brief description of responsibilities, along with the minimum level of education and

experience. Table E.4 presents descriptions for staff members that may be considered optional personnel or, in some cases, represent necessary support that is provided by personnel with other position titles. Table E.5 indicates the minimum education and experience for laboratory technical staff members. In some cases, specific training may add to or be substituted for the listed education or experience requirement. Training may come in a number of forms, such as instrument-specific classes offered by a manufacturer, to operational or safety programs given by outside trainers or the laboratory's own staff.

TABLE E.3 — Laboratory technical supervisory personnel listed by position title and examples for suggested minimum qualifications

All personnel are responsible to perform their work to meet all terms and conditions of the contract

Technical Supervisory Personnel		
Position Title and Responsibilities	**Education**	**Experience**
Radiochemical Laboratory Supervisor, Director, or Manager. Responsible for all technical efforts of the radiochemical laboratory.	Minimum of bachelor's degree in any scientific/engineering discipline, with training in radiochemistry, radiation detection instrumentation, statistics, and QA.	Minimum of three years of radioanalytical laboratory experience, including at least one year in a supervisory position. Training in laboratory safety, including radiation safety.
Quality Assurance Officer Responsible for overseeing the quality assurance aspects of the data and reporting directly to upper management.	Minimum of bachelor's degree in any scientific/engineering discipline, with training in physics, chemistry, and statistics.	Minimum of three years of laboratory experience, including at least one year of applied experience with QA principles and practices in an analytical laboratory or commensurate training in QA principles.

TABLE E.4 — Laboratory technical personnel listed by position title and examples for suggested minimum qualifications and examples of optional staff members

Optional Technical Personnel		
Position Title and Responsibilities	**Education**	**Experience**
Systems Manager Responsible for the management and quality control of all computing systems; generating, updating, and quality control for deliverables.	Minimum of bachelor's degree with intermediate courses in programming, information management, database management systems, or systems requirements analysis.	Minimum of three years experience in data or systems management of programming, including one year experience with the software being utilized for data management and generation of deliverables.
Programmer Analyst Responsible for the installation, operation, and maintenance of software and programs, generating, updating, and quality of controlling analytical databases and automated deliverables.	Minimum of bachelor's degree with intermediate courses in programming, information management, information systems, or systems requirements analysis.	Minimum of two years experience in systems or applications programming, including one year experience with the software being utilized for data management and generation of deliverables.

TABLE E.5 — Laboratory technical personnel listed by position title and examples for suggested minimum qualifications

All personnel are responsible to perform their work to meet all terms and conditions of the contract.

Technical Staff		
Position Title	**Education**	**Experience**
Gamma Spectrometrist	Minimum of bachelor's degree in chemistry or any physical scientific/engineering discipline. Training courses in gamma spectrometry.	Minimum two years experience in spectrometric data interpretation. Formal training or one year experience with spectral analysis software used to analyze data.
Alpha Spectrometrist	Minimum of bachelor's degree in chemistry or any physical scientific/engineering discipline. Training courses in alpha spectrometry.	Formal training or one year experience with spectral analysis software used to analyze data.
Radiochemist	Minimum of bachelor's degree in chemistry or any physical scientific/engineering discipline. In lieu of the educational requirement, two years of additional, equivalent radioanalytical experience may be substituted.	Minimum of two years experience with chemistry laboratory procedures, with at least one year of radiochemistry in conjunction with the educational qualifications, including (for example): 1) Operation and maintenance of radioactivity counting equipment; 2) Alpha/gamma spectrometric data interpretation; 3) Radiochemistry analytical procedures; and 4) Sample preparation for radioactivity analysis.
Counting Room Technician	Minimum of bachelor's degree in chemistry or any scientific/engineering discipline.	Minimum of one year experience in a radioanalytical laboratory.
Laboratory Technician	Minimum of high school diploma and a college level course in general chemistry or equivalent—or college degree in another scientific discipline (e.g., biology, geology, etc.)	Minimum of one year experience in a radioanalytical laboratory.

E.4.3 Instrumentation

A proposer's laboratory must have in place and in good working order the types and required number of instruments necessary to perform the work advertised by the agency. Specific factors are noted in the RFP, such as: an estimate for the number of samples, length of the contract, and expected turnaround times which influence the types of equipment needed to support the contract.

Analytical work can be viewed as a function of current technology. Changes may occur from time to time, especially in relation to scientific advancements in equipment, software, etc. Instrumentation represents the mechanical interface between prepared samples and the data generated in the laboratory. The capacity to process larger and larger numbers of samples while sustaining the desired level of analytical sensitivity and accuracy is ultimately a function of the laboratory's equipment, and the knowledge and experience of the individuals who operate and

maintain the instruments. Additional support for the laboratory's on-line activities or the state of readiness to maintain a constant or an elevated peak work load comes in the form of back-up instruments that are available at all times. Information concerning service contracts that provide repairs or replacement when equipment fails to perform is important to meeting contract obligations. Demonstrating that this support will be in place for the duration of the contract is a key element for the proposer to clearly describe in a proposal.

E.4.3.1 Type, Number, and Age of Laboratory Instruments

A description of the types of instruments at a laboratory is an important component of the proposal. The number of each type of instrument available for the proposed work should be indicated in the proposal. This includes various counters, detectors, or other systems used for radioanalytical work. A complete description for each instrument might include the age or acquisition date. This information may be accompanied by a brief description indicating the level of service an instrument provides at its present location.

E.4.3.2 Service Contract

The types and numbers of service contracts may vary depending on the service provider. Newly purchased instruments will be covered by a manufacturer's warranty. Other equipment used beyond the initial warranty period may either be supported by extensions to the manufacturer's warranties or by other commercial services that cover individual instrument or many instruments under a site-wide service contract. Whatever type of support is in place, the contractor will need to state how having or not having such service contracts affects the laboratory's ability to meet the terms of the contract and the potential impact related to the SOW.

E.4.4 Narrative to Approach

A proposal can "speak" to the agency's evaluation team by providing a logical and clearly written narrative of how the proposer will attend to every detail listed in the RFP. This approach conveys key information in a readable format to relate a proposer's understanding, experience, and working knowledge of the anticipated work. In this way, the text also illustrates how various components of the proposal work together to contribute to a unified view of the laboratory functions given the proposed work load as described in the RFP and as detailed in the SOW. The next four sections provide examples of proposal topics for which the proposer may apply a narrative format to address how the laboratory is qualified to do the proposed work.

E.4.4.1 Analytical Methods or Protocols

The proposer should list all proposed methods they plan to use. The proposal should also furnish all required method validation documentation to gain approval for use. When addressing use of

methods, the proposer can describe how a method exhibits the best performance and also offer specific solutions to meet the agency's needs.

E.4.4.2 Meeting Contract Measurement Quality Objectives

The agency's planning process started with a review of questions and issues concerned with generating specific project APSs/MQOs. Stating how a proposer intends to meet the APSs/ MQOs data quality requirements adds an important section to the proposal. This allows the competing laboratories to demonstrate that they understand the requirements of the contract and their individual approaches to fulfilling these requirements. Further evidence in support of the proposer's preparations to meet or exceed the agency's data quality needs is generally covered in a contract laboratory's quality manual (Section E.4.5).

E.4.4.3 Data Package

The proposer responds to the RFP by stating how data will be processed under the contract. A narrative describing the use of personnel, equipment, and facilities illustrates every step in obtaining, recording, storing, formatting, documenting and reporting sample information and analytical results. The specific information related to all these activities and the required information as specified by the SOW is gathered into a data package. For example, a standard data package includes a case narrative, the results (in the format specified by the agency), a contractor data review checklist, any nonconformance memos resulting from the work, agency and contractor-internal chains of custody, sample and quality control (QC) sample data (this includes a results listing, calculation file, data file list, and the counting data) and continuing calibration data, and standard and tracer source-trace information, when applicable. At the inception of a project, initial calibration data are provided for detectors used for the work. If a detector is recalibrated, or a new detector is placed in service, initial calibration data are provided whenever those changes apply to the analyses in question.

Specific data from the data package may be further formatted in reports, including electronic formats, as the required deliverables which the contractor will send to the agency. The delivery of this information is also specified according to a set schedule.

E.4.4.4 Schedule

The RFP will provide information that allows the proposer to design a schedule that is tailored to the agency's need. For example, samples that are part of routine monitoring will arrive at the laboratory and the appropriate schedule reflects a cycle of activity from sample preparation to delivering a data package to the agency. This type of schedule is repeatedly applied to each set of samples. Other projects, surveys, or studies may follow a time line of events from start to completion, with distinct sets of samples and unique needs that arise at specific points in time. The proposer will initially outline a schedule that may utilize some cycling of activities at various

stages of the work, but overall the nature of the work may change from stage to stage. The schedule in this case will reflect how the contractor expects to meet certain unique milestones on specific calendar dates.

Some projects will have certain requirements to process samples according to a graded processing schedule. The SOW should provide the requirements for the radiological holding time and sample processing turnaround time. Radiological holding time refers to the time required to process the sample—the time differential from the sample receipt date to the final sample matrix counting date. The sample processing turnaround time normally means the time differential from the receipt of the sample at the laboratory (receipt date) to the reporting of the analytical results to the agency (analytical report date). As such, the turnaround time includes the radiological holding time, the time to generate the analytical results, and the time to report the results to the agency.

Typically, three general time-related categories are stated: routine, expedited, and rush. Routine processing is normally a 30-day turnaround time, whereas expedited processing may have a turnaround time greater than five days but less than 30 days. Rush sample processing may have a radiological holding time of less than five days. For short-lived nuclides, the RFP should state the required radiological holding time, wherein the quantification of the analyte in the sample must be complete within a certain time period. The reporting of such results may be the standard 30-day turnaround time requirement. The agency should be reasonable and technically correct in developing the required radiological holding and turnaround times.

The RFP should specify a schedule of liquidated or compensatory damages that should be imposed when the laboratory is noncompliant relative to technical requirements, radiological holding times, or turnaround times.

E.4.4.5 Sample Storage and Disposal

The RFP should specify the length of time the contractor must store samples after results are reported. In addition, it should state who is economically and physically responsible for the disposal of the samples. The laboratory should describe how the samples will be stored for the specified length of time and how it plans to dispose of the samples in accordance with local, state and federal regulations.

E.4.5 Quality Manual

Only those radiochemistry laboratories that adhere to well-defined quality procedures—pertaining to data validation, internal and external laboratory analytical checks, instrument precision and accuracy, personnel training, and setting routine laboratory guidelines—can insure the highest quality of scientifically valid and defensible data. In routine practice, a laboratory

prepares a written description of its quality manual that addresses, 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 quality manual may be a separately prepared document that may incorporate or reference already available and approved laboratory standard operating procedures (SOPs). This manual provides sufficient detail to demonstrate that the contractor's measurements and data are appropriate to meet the MQOs and satisfy the terms and conditions of the contract. The manual should clearly state the objective of the SOP, how the SOP will be executed, and which performance standards will be used to evaluate the data. Work-related requirements based on quality assurance are also an integral part of the SOW.

When a proposal is submitted for review, the contracting laboratory generally sends along a current copy of its quality manual. Additional details pertaining to the content of a quality manual can be found in NELAC (2002), ANSI/ASQC E-4, EPA (1993, 2001, 2002), ISO/IEC 17025, and MARSSIM (2000).

E.4.6 Licenses and Accreditations

All laboratories must have appropriate licenses from the U.S. Nuclear Regulatory Commission (NRC) or other jurisdictions (Agreement State, host nation, etc.) to receive, possess, use, transfer, or dispose of radioactive materials (i.e., those licensable as indicated in 10 CFR 30.70, Schedule A—Exempt Concentrations). A license number and current copy of a laboratory's licenses are typically requested with paperwork that one submits to obtain radionuclide materials—for example, when ordering and arranging to use laboratory standards. Overall, a laboratory's license permits work with certain radionuclides and limits to the quantity of each radionuclide at the laboratory. A proposer's license should allow for new work with the types and anticipated amounts of radionuclides as specified in an RFP. Part of the licensing requirement ensures that the laboratory maintains a functioning radiation safety program and properly trains its personnel

in the use and disposal of radioactive materials. For more complete information on license requirements, refer to either the NRC, the appropriate state office, or 10 CFR 30.

The laboratory may need to be certified for radioassays by the state in which the lab resides. The RFP should request a copy of the current standing certification(s) to be submitted with the proposal. If the agency expects a laboratory to process samples from numerous states across the United States, then additional certifications for other states may or will be required. To request that a proposer arrange for certification in multiple states prior to submitting a proposal may be viewed as placing an unfair burden on a candidate laboratory who as yet to learn if it will be awarded a contract. Additional fees, for each state certification, potentially add to a proposer's cost to simply present a proposal. In such cases, an agency may indicate that additional certification(s)—above that already held for the laboratory's state of residence—may be required once the contract is awarded and just prior to initiating the work.

E.4.7 Experience

The contractor, viewed as a single entity made of all its staff members, may have an extensive work history as is exemplified through the number and types of projects and contracts that were previously or are currently supported by its laboratory services. This experience is potentially an important testimonial to the kind of work the contractor is presently able to handle with a high degree of competence. The agency's evaluation team will review this information relative to the need(s) stated in the RFP. The more applicable the track record, the stronger a case the proposer has when competing for the award.

E.4.7.1 Previous or Current Contracts

In direct relation to the preceding section, the proposer's staff should respond directly to the RFP when asked to provide a list of contracts previously awarded and those they are presently fulfilling. Of primary importance, the list should contain contracts that are similar to the one under consideration (i.e., similar work load and technical requirements), with the following information:

- Name of the company or agency awarding the contract;
- Address;
- Phone number;
- Name of contact person; and
- Scope of contract.

E.4.7.2 Quality of Performance

The agency's TEC (Section E.5.1) is likely to check a laboratory's results for its participation in a proficiency program which is sponsored by one of several federal agencies. For example, the

U.S. Department of Energy (DOE), and National Institute of Standards and Technology (NIST) offer proficiency programs. Records for the laboratory's results may be reviewed to cover a number of years. This review indicates quality and consistency in relation to the types of samples that the federal agency sends to each laboratory. Thus, at designated times during each year, a laboratory will receive, process, and later report findings for proficiency program samples. This routine is also required for certification by an agency, such as the U.S. Environmental Protection Agency (EPA) for drinking water analysis. In this case, to obtain or maintain a certification, the laboratory must pass (i.e., successfully analyze) on the basis of a specific number of the total samples.

E.5 Proposal Evaluation and Scoring Procedures

The initial stages of the evaluation process separate technical considerations from cost. Cost will enter the selection process later on. The agency's TEC will consider all proposals and then make a first cut (Table E.6 and Section E.5.3 below), whereby some proposals are eliminated based on the screening process. This selection from among the candidates is based on predetermined criteria that are related to the original MQOs and how a proposer's laboratory is technically able to support the contract. A lab that is obviously unequipped to perform work according to the SOW is certain to be dropped early in the selection process. In some cases, the stated ability to meet the analysis request should be verified by the agency, through pre-award audits and proficiency testing, as described below. Letters notifying unsuccessful bidders may be sent at this time. For information concerning a proposer's response to this letter, see Section E.5.7.

E.5.1 Evaluation Committee

The agency personnel initially involved in establishing a new contract and starting the selection process include the Contracting Officer (administrative, nontechnical) and Contracting Officer's Representative (technical staff person advising the Contracting Officer). Once all proposals are accepted by the agency, a team of technical staff members score the technical portion of the proposal. The team is lead by a chairperson who oversees the activities of this TEC. It is recommended that all members of the TEC have a technical background relevant to the subject matter of the contract.

One approach to evaluation includes sending copies of all proposals to each member of the committee for individual scoring (Table E.6). The agency, after an appropriate length of time, may conduct a meeting or conference call to discuss the scores and reach a unified decision. Using this approach, each proposal is given a numerical score and these are listed in descending order. A "break-point" in the scores is chosen. All candidates above this point are accepted for a continuation of the selection process. Those below the break point may be notified at this point in time. Note that evaluations performed by some agencies may follow variations on this scoring and decision process.

The TEC must have a complete technical understanding of the subject matter related to the proposed work and the contract that is awarded at the end of the selection process. These individuals are also responsible for responding to any challenge to the agency's decision to award the contract. Their answers to such challenges are based on technical merit in relation to the proposed work (Section E.5.7).

E.5.2 Ground Rules — Questions

The agency's solicitation should clearly state if and when questions from an individual proposer will be allowed during the selection process. Information furnished in the agency's response is simultaneously sent to all competing laboratories.

E.5.3 Scoring/Evaluating Scheme

The agency should prepare an RFP that includes information concerning scoring of proposals or weights for areas of evaluation. This helps a proposer to understand the relative importance of specific sections in a proposal and how a proposal will be scored. In this case, the method of evaluation and the scoring of specific topic areas is outlined in the solicitation. If this information is not listed in the solicitation and because evaluation formats differ agency to agency, proposers may wish to contact the agency for additional agency-specific details concerning this process.

An agency may indicate the relative weight an evaluation area holds with regard to the proposed work for two principle reasons. First, the request is focused to meet a need for a specific type of work for a given study, project, or program. This initially allows a proposer to concentrate on areas of greatest importance. Second, if the contractor submits a proposal that lacks sufficient information to demonstrate support in a specific area, the agency can then indicate how the proposal does not fulfill the need as stated in the request.

Listed below is an example of some factors and weights that an agency might establish before an RFP is distributed:

Description	Weight
Factor I . . . .Technical Merit	25
Factor II . . .Proposer's Past Performance	25
Factor III . . .Understanding of the Requirements	15
Factor IV . .Adequacy and Suitability of Laboratory Equipment and Resources	15
Factor V . . .Academic Qualifications and Experience of Personnel	10
Factor VI . .Proposer's Related Experience	10

The format presented above assigns relative weights for each factor—with greater weight given to more important elements of the proposal. Technical merit (Factor I) includes technical

approach, method validation, and the ability to meet the MQOs, etc. Factor II includes how well the proposer performed in previous projects or related studies. A proposer's understanding (Factor III) is demonstrated by the laboratory's programs, commitments as well as certifications, licenses, etc., to ensure the requirements of the RFQ will be met. Adequacy and suitability (Factor IV) is generally an indication that the laboratory is presently situated to accept samples and conduct the work as proposed. Factor V focuses on topics covered previously in Section E.4.2 while the proposer's experience (Factor VI) is considered in Section E.4.7.

An agency may use a Technical Evaluation Sheet—in conjunction with the Proposal Evaluation Plan as outlined in the next section (Table E.6)—to list the total weight for each factor and to provide a space for the evaluator's assigned rating. The evaluation sheet 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 briefly discussed in the next three sections (E.5.3.1 to E.5.3.3)

E.5.3.1 Review of Technical Proposal and Quality Manual

Each bidding-contractor laboratory will be asked to submit a technical proposal and a copy of its quality manual. This document is intended to address all of the technical and general laboratory requirements. 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.

Table E.6 is an example of a proposal evaluation plan (based on information from the U.S. Geological Survey). This type of evaluation can be applied to proposals as they are considered by the TEC.

TABLE E.6 — Example of a proposal evaluation plan

Proposal Evaluation
Objective: To ensure impartial, equitable, and comprehensive evaluation of proposals from contractors desiring to accomplish the work as outlined in the Request for Proposals and to assure selection of the contractor whose proposal, as submitted, offers optimum satisfaction of the government's objective with the best composite blend of performance, schedules, and cost.
Basic Philosophy: To obtain the best possible technical effort which satisfies all the requirements of the procurement at the lowest overall cost to the government.
Evaluation Procedures
1. Distribute proposals and evaluation instructions to Evaluation Committee.
2. Evaluation of proposals individually by each TEC member. Numerical values are recorded with a concise narrative justification for each rating.

3. The entire committee by group discussion prepares a consensus score for each proposal. Unanimity is attempted, but if not achieved, the Chairperson shall decide the score to be given.

4. A Contract Evaluation Sheet listing the individual score of each TEC member for each proposal and the consensus score for the proposal is prepared by the Chairperson. The proposals are then ranked in descending order.

5. The Chairperson next prepares an Evaluation Report which includes a Contract Evaluation Sheet, the rating sheets of each evaluator, a narrative discussion of the strong and weak points of each proposal, and a list of questions which must be clarified at negotiation. This summary shall be forwarded to the Contracting Officer.

6. If required, technical clarification sessions are held with acceptable proposers.

7. Analysis and evaluation of the cost proposal will be made by the Contracting Officer for all proposals deemed technically acceptable. The Chairperson of the TEC will perform a quantitative and qualitative analysis on the cost proposals or those firms with whom cost negotiations will be conducted.

Evaluation Criteria

The criteria to be used in the evaluation of this proposal are selected before the RFP is issued. In accordance with the established agency policy, TEC members prepare an average or consensus score for each proposal on the basis of these criteria and only on these criteria.

A guideline for your numerical rating and rating sheets with assigned weights for each criteria are outlined next under Technical Evaluation Guidelines for Numerical Rating.

Technical Evaluation Guidelines for Numerical Rating

1. Each item of the evaluation criteria will be based on a rating of 0 to 10 points. Therefore, each evaluator will score each item using the following guidelines:

    a. *Above normal*: 9 to 10 points (a quote element which has a high probability of exceeding the expressed RFP requirements).

    b. *Normal*: 6 to 8 points (a quote element which, in all probability, will meet the minimum requirements established in the RFP and Scope of Work).

    c. *Below normal*: 3 to 5 points (a quote element which may fail to meet the stated minimum requirements, but which is of such a nature that it has correction potential).

    d. *Unacceptable*: 0 to 2 points (a quote element which cannot be expected to met the stated minimum requirements and is of such a nature that drastic revision is necessary for correction).

2. Points will be awarded to each element based on the evaluation of the quote in terms of the questions asked.

3. The evaluator shall make no determination on his or her own as to the relative importance of various items of the criteria. The evaluator must apply a 0 to 10 point concept to each item without regard to his or her own opinion concerning one item being of greater significance than another. Each item is given a predetermined weight factor in the Evaluation Plan when the RFP is issued and these weight factors must be used in the evaluation.

E.5.3.2 Review of Laboratory Accreditation

A copy of the current accreditation(s) should be submitted with the proposal. The agency should confirm the laboratory's accreditation by contacting the federal or state agency that provided the accreditation. In some cases, a public listing or code number is provided. Confirming that a specific code number belongs to a given laboratory will require contacting the agency that issued the code.

E.5.3.3 Review of Experience

The laboratory should furnish references in relation to its past or present work (Section E.4.7.1). To the extent possible, this should be done with regard to contracts or projects similar in composition and size to the proposed project. One or more members of the TEC are responsible for developing a list of pertinent questions and then contacting each reference listed by the proposer. The answers obtained from each reference are recorded for use later in the evaluation process. In some cases, the laboratory's previous performance for the same agency should be given special consideration.

E.5.4 Pre-Award Proficiency Samples

Some agencies may elect to send proficiency or performance testing (PT) 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; Chapter 6, *Section and Application of an Analytical Method*) be used when available. The matrix of which the PT sample is composed must be well characterized and known to the agency staff who supply the sample to the candidate laboratory. For example, if an agency is concerned with drinking water samples, then the agency's laboratory may use its own source of tap water as a base for making PT samples. This water, with or without additives, may be supplied for this purpose.

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 lab failing to submit results should be automatically disqualified. The results should be evaluated and each lab given a score. This allows the agency to narrow the selection further—after which only two or three candidate laboratories are considered.

At this point, two additional selection phases remain. A visit to each candidate's facilities comes next (Section E.5.5) and thereafter, once all technical considerations are reviewed, the cost of the contractor's service is examined last (Section E.5.6).

E.5.5 Pre-Award Audit

A pre-award audit, which may be an initial audit, is often performed to provide assurance that a selected laboratory is capable of performing the required analyses in accordance with the SOW. In other words, *is the laboratory's representation (proposal) realistic when compared to the actual facilities?* To answer this question, auditors will be looking to see that a candidate laboratory appears to have all the required elements to meet the proposed contract's needs. In some cases, it may be appropriate to conduct both a pre-award audit, followed by an evaluation after the work begins (see Section E.6.7 for information on ongoing laboratory evaluations).

The two or three labs with the highest combined scores (for technical proposals and proficiency samples) may be given an on-site audit.

The pre-award audit is a key evaluating factor that is employed before the evaluation committee makes a final selection. Many federal agencies, including DOE, EPA, and USGS, have developed forms for this purpose. Some of the key items to observe during an audit include:

- Sample Security – Will the integrity of samples be maintained for chain of custody? If possible, examine the facility's current or past chain-of-custody practice.

- Methods – Are copies of SOP's available to every analyst? In some cases, one may check equations used to identify and quantitate the radionuclides of interest. Additional concerns include the potential for interferences, total propagated uncertainty, decision levels, and minimum detectable concentrations.

- Method Validation Documentation – Verify the method validation documentation provided in the response to the RFP. Have there been any QA/QC issues related to the methods? Are the identified staff (provided in the RFP) qualified to perform the methods?

- Adherence to SOPs – This may include looking to see that sample preparation, chemical analysis, and radiometric procedures are performed according to the appropriate SOP.

- Internal QC – Check the files and records.

- External QC/PT samples – Check files and records pertaining to third-party programs.

- Training – Check training logs. Examine analysts' credentials, qualifications, and proficiency examination results.

- Instrumentation – Check logs. Are instruments well maintained, is there much down time, are types and numbers listed in technical proposal correct? Look for QC chart documentation.

- Instrumentation – Calibration records. Do past and current calibration records indicate that the laboratory's instruments are capable of providing data consistent with project needs? Look at instrumentation characteristics, including resolution, detection efficiency, typical detection limits, etc. Are materials that are traceable to a national standards organization (such as NIST in the United States) used for detector calibration and chemical yield determinations?

- Personnel – Talk with and observe analysts. Verbal interaction with laboratory staff during an audit helps auditors to locate the information and likewise provide evidence for the knowledge and understanding of persons who conduct work in the candidate laboratory.

- Log-In – Is this area well-organized to reduce the possibility of sample mix-ups?

- Tracking – Is there a system of tracking samples through the lab?

Information about each laboratory may be gathered in various ways. One option available to the agency is to provide each candidate laboratory with a list of questions or an outline for information that will be collected during the audit (Table E.7). The agency's initial contact with the laboratory can include a packet with information about the audit and questions that the laboratory must address prior to the agency's on-site visit. For example, from the checklist presented in Table E.7, one can see the laboratory will be asked about equipment. In advance of the audit, laboratory personnel can create a listing of all equipment or instruments that will be used to support the contract. Table E.7 also indicates information to be recorded by the auditors during the visit. The audit record includes the agency's on-site observations, along with the laboratory's prepared responses.

TABLE E.7— Sample checklist for information recorded during a pre-award laboratory audit

Laboratory:
Date:
Auditors:
1.
2.

A. Review packet that was sent to laboratory for completion:
1. Laboratory Supervisor
2. Laboratory Director
3. Current Staff
4. Is the laboratory responsible for all analyses? If not, what other laboratory(s) is (are) responsible?
5. Agency responsible for [drinking water] program in the state.
6. Does the laboratory perform analyses of environmental samples around nuclear power facilities, or from hospitals, colleges, universities, or other radionuclide users?
7. Agency responsible for sample collections in item 6.

B. Laboratory Facilities:
1. Check all items in the laboratory packet.

TABLE E.7— Sample checklist for information recorded during a pre-award laboratory audit

2. Comments
3. Is there a Hot Laboratory or a designated area for samples from a nuclear power facility that would represent a nuclear accident or incident? Is this documented in the SOP or QA Manual?

C. Laboratory Equipment and Supplies:
1. Check all items on the laboratory packet. Includes analytical balances, pH meters, etc.
2. Comments
3. Radiation counting instruments:
   a. Thin window gas-flow proportional counters
   b. Windowless gas-flow proportional counters
   c. Liquid scintillation counter
   d. Alpha scintillation counter
   e. Radon gas-counting system
   f. Alpha spectrometer
   g. Gamma spectrometer systems:
      1. Ge (HPGe) detectors
      2. NaI detectors
      3. Multichannel analyzer(s)

D. Analytical Methodology:
1. Check all items on the laboratory packet.
2. Comments

E. Sample Collection, Handling, and Preservation:
1. Check all items on the laboratory packet.
2. Comments

F. Quality Assurance Section:
1. Examine laboratory SOP
   a. Comments

2. Examine laboratory's quality manual
   a. Comments

3. Performance Evaluation Studies (Blind)
   a. Comments and results

4. Maintenance records on counting instruments and analytical balances.
   a. Comments and results

5. Calibration data
   a. Gamma Spectrometer system
      1. Calibration source
      2. Sufficient energy range
      3. Calibration frequency
      4. Control charts
         a. Full Peak Efficiency
         b. Resolution
         c. Background

TABLE E.7— Sample checklist for information recorded during a pre-award laboratory audit

b. Alpha/Beta counters
   1. Calibration source
   2. Calibration frequency
   3. Control charts
      a. Alpha
      b. Beta
      c. Background

c. Radon counters
   1. Calibration source
   2. Frequency of radon cell background checks

d. Liquid Scintillation Analyzer
   1. Calibration sources
   2. Calibration frequency
   3. Control charts
      a. H-3
      b. C-14
      c. Background
      d. Quench

6. Absorption and Efficiency curves:
   a. Alpha absorption curve
   b. Beta absorption curve
   c. Ra-226 efficiency determination
   d. Ra-228 efficiency determination
   e. Sr-89, Sr-90, and Y-90 efficiency determinations
   f. Uranium efficiency determination

7. Laboratory QC Samples
   a. Spikes
   b. Replicates/duplicates
   c. Blanks
   d. Cross check samples
   e. Frequency of analysis
   f. Contingency actions if control samples are out of specification
   g. Frequency of analysis

E. Records and Data Reporting
   1. Typical data package
   2. Electronic data deliverable format
   3. Final data report

H. Software Verification and Validation
   1. Instrumentation and Equipment Control and Calibrations
   2. Analytical Procedure Calculations/Data Reduction
   3. Record Keeping/Laboratory/Laboratory Information Management System/Sample Tracking
   4. Quality Assurance Related — QC sample program/instrument QC

E.5.6 Comparison of Prices

To this point, the selection process focuses on technical issues related to conducting work under the proposed contract. Keeping this separate from cost considerations simplifies the process and helps to sustain reviewer objectivity. Once the scoring of labs is final, the price of analyses may be reviewed and compared. Prices are now considered along with inspection results. This part of the process is best performed by technical personnel, including members of the TEC who work in either a laboratory or the field setting, and who possess the knowledge to recognize a price that is reasonable for a given type of analysis. Various scenarios may apply where prices differ:

- Candidates are dropped generally if their proposed prices are extreme.

- Laboratories that score well—aside from their prices that may still be on the high side—are given an opportunity to rebid with a best and final cost. This lets laboratories know they have entered the final stage of the selection process.

A final ranking is based on the technical evaluation, including the proficiency examination and audit if conducted, and the best-and-final prices submitted by each laboratory.

While there is no way to determine how evaluations may be conducted in the future, some extra consideration may be given to proposals that offer greater technical capabilities (i.e., those that house state-of-the-art or high-tech analytical services) as opposed to fulfilling the minimum requirements of the RFP.

E.5.7 Debriefing of Unsuccessful Vendors

At an appropriate time in the selection process, all unsuccessful bidders are sent a letter outlining the reasons that they were not awarded the contract. As noted previously, the RFP should be very explicit in illustrating what a proposal should contain and which areas carry more or less weight with regard to the agency's evaluation. If so, the agency is able to provide a written response to specifically identify areas of the proposal where the contractor lacks the appropriate services or is apparently unable to present a sufficiently strong case documenting an ability to do the work. Also, as stated previously, the proposer must present as clear a case as possible and write into the proposal all relevant information. A simple deletion of key information will put a capable proposer out of the running in spite of the experience, support, and services they are able to render an agency.

If a contractor wishes an individual debriefing, the agency can arrange to have the TEC meet with the contractor's representatives. This meeting allows for an informal exchange to further explore issues to the satisfaction of the proposer. This exchange may offer the agency an opportunity to restate and further clarify the expected minimum qualifications that are required of the proposer.

A more formal approach contesting the agency's decision follows after a protest is lodged by the contractor. In this case, the agency's TEC and the contractor's representatives are accompanied by legal council for both sides.

E.6 The Award

The selection process ends when the agency personnel designate which contractor will receive the award. Several steps follow in advance of formally presenting the award. This essentially includes in-house processing, a review by the agency's legal department, and a final review by the contract staff. These activities verify that the entire selection process was followed properly and that the contract's paperwork is correct. The agency's contracts office then signs the proper documents and the paperwork is sent to the contractor. The contract becomes effective as of the date when the government's contracting officer signs.

E.7 For the Duration of the Contract

After the award is made, the agency enters into a working relationship with the contract laboratory and work begins. Over the period of the contract, the agency will send samples, receive deliverables, and periodically check the laboratory's performance. The work according to the SOW and the activities associated with performance checks and laboratory evaluations are topics covered beginning with the next section. Furthermore, as data are delivered to the agency, invoices will be sent by the contractor to the agency. The agency will process the invoices in steps: that receipt of data is initially confirmed, the results are appropriate (i.e., valid), and finally that the invoice is paid. This activity may occur routinely as invoices arrive—weekly, monthly, or at some other time interval throughout the course of a contract.

Keep in mind that the structured planning process is iterative in nature and may come into play at any point during a contract period. For example, federal or state laboratories engaging contract-support services may be involved in routine monitoring of numerous sampling sites. For sets of samples that are repeatedly taken from a common location over the course of years, only the discovery of unique results or change in performance-based methods may instigate an iteration and a review of the MQOs. For other types of projects, such as a location undergoing a MARSSIM-site survey, the project plan may change as preliminary survey work enters a period of discovery—e.g., during a scoping or characterization survey (MARSSIM, 2000). Even during a final status survey, discovery of some previously unknown source of radioactive contamination may force one to restate not only the problem, but to reconsider every step in the planning process. Modification of a contract may be necessary to address these circumstances.

E.7.1 Managing a Contract

Communication is key to the successful management and execution of the contract. Problems, schedule, delays, potential overruns, etc., can only be resolved quickly if communications between the laboratory and agency are conducted promptly.

A key element in managing a contract is the timely verification (assessment) 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 which are unusable. Note that some sample matrices and processing methods can be problematic for even the best laboratories. Thus the contract manager must be able to discern between failures due to legitimate reasons and poor laboratory performance.

E.7.2 Responsibility of the Contractor

First and foremost, the responsibility of the laboratory is to meet the performance criteria of the contract. If the SOW is appropriately written, this provides guidance necessary to ensure the data produced will meet the project planning goals and be of definable quality. Similarly, the laboratory must communicate anticipated or unforeseen problems as soon as possible. Again, this could easily occur with complex, unusual, or problematic sample matrices. Communication is vital to make sure that matrix interferences are recognized as early as possible, and that subsequent analyses are planned accordingly.

The laboratory's managers must plan the analysis—that is, have supplies, facilities, staff, and instruments available as needed—and schedule the analysis to meet the agency's due date. In the latter case, a brief buffer period might be included for unanticipated problems and delays, thus allowing the laboratory the opportunity to take appropriate corrective action on problems encountered during an analysis.

E.7.3 Responsibility of the Agency

During the period of the contract, the agency is responsible for employing external quality assurance oversight. Thus the performance of the laboratory should be monitored continually to insure the agency is receiving compliant results. Just because a laboratory produces acceptable results at the beginning of its performance on a contract does not necessarily mean that it will continue to do so throughout the entire contract period. For example, the quality of the data can degenerate at times when an unusually heavy workload is encountered by an environmental laboratory. One way to monitor this performance is to review the results of internal and external quality assurance programs. This may in part take the form of site visits (including onsite audits), inclusion of QC samples, evaluation of performance in Performance Evaluations or intercomparison programs, desk audits, and data assessments.

E.7.4 Anomalies and Nonconformance

The contractor must document and report all deviations from the method and unexpected observations that may be of significance to the data 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. The agency's reviewer should assure that the reason(s) given for the departures are clearly explained and are credible. The repeated reporting of the same deviation may be an indication of internal laboratory problems.

E.7.5 Laboratory Assessment

As work under a contract progresses over time, there are two principle means to assess a laboratory's performance: by having the laboratory process quality control samples (Section E.7.5.1 and E.7.5.2), and by agency personnel visiting the laboratory to conduct on-site evaluations (Section E.7.5.3).

E.7.5.1 Performance Testing and Quality Control Samples

A laboratory's performance is checked in one of several ways, including the use of agency PT samples, the laboratory's QC samples, laboratory participation in a performance evaluation program, agency certification program, and through agency audits, which may include an on-site visit.

There are several approaches to determining that an analysis is accurate and that the data reflect a true result. One check on each analysis comes from the laboratory's own QC measures. The contractor will routinely run standards, prepared spiked samples, and blanks, along with the samples submitted by the agency. Calibrations are also performed and a laboratory technician is expected to record information to document instrument performance.

Another avenue for monitoring performance comes with measures taken by the agency, including the incorporation of a number of double-blind PT samples, with each batch of samples sent to the contract laboratory. The preparation of double-blind PT samples for matrices other than water is difficult. A sample designated as a *blind PT sample* is one that the contractor knows is submitted by the agency for performance testing purposes. A *double-blind sample* is presented to the laboratory as if it were just another sample with no indication that this is for performance testing purposes. In the former case, the samples may be labeled in such a manner that the laboratory recognizes these as PT samples. In the latter case, unless the agency takes steps to use very similar containers and labeling as that for the field samples, the laboratory may recognize the double-blind PT samples for what they are. This in effect compromises the use of a double-blind sample. In each case, the agency knows the level or amount of each radionuclide in the blind sample.

When the analysis for a set of samples is complete and data are sent to the agency, the agency in turn checks the results for the PT samples and then performs data validation. In the case of characterization studies, one may continue to check results for PT samples, but data validation packages may not be required. If the double-blind results are not within reasonable limits, the agency will need to examine how these specific data may indicate a problem. In the meantime, work on subsequent sample sets cannot go forward until the problem is resolved. Some or all samples in the questionable batch may need to be reanalyzed depending on the findings for the PT samples. This is a case where storage of samples by the laboratory—e.g., from three to six months after analyses are performed—allows the agency to back track and designate specific samples for further or repeated analyses. The one exception to going back and doing additional analyses arises for samples containing radionuclides with short half lives. This type of sample requires a more immediate assessment to allow for repeated analyses, if needed.

Where data validation is required, the agency will routinely look at results for the PT samples that are added to the sample sets collected in the field. An additional QA measure includes a routine examination—for example, on a monthly or quarterly basis—of the laboratory's results for their own internal QC samples. This includes laboratory samples prepared as spikes, duplicates, and blanks that are also run along with the agency samples.

The agency can also schedule times to monitor a contractor laboratory's participation in a performance evaluation program—for example, those supported by the DOE, EPA, NIST, or NRC. Each laboratory, including the agency's own facilities, are expected to participate in such programs. The agency will also check to see if a laboratory's accreditation (if required) is current and this is something that should be maintained along with participation in a federally sponsored performance evaluation program. In general, the states accredit laboratories within their jurisdiction.

E.7.5.2 Laboratory Performance Evaluation Programs

Participating in an interlaboratory testing program (such as the PE programs mentioned in Section E.7.5.1) is the best way for a laboratory to demonstrate or an agency to evaluate a laboratory's measurement quality in comparison to other laboratories or to performance acceptance criteria. Furthermore, because MARLAP promotes consistency among radiochemistry laboratories, it is scientifically, programmatically, and economically advantageous to embrace the concept of a common basis for radioanalytical measurements—a measurement quality system that is ultimately traced to a national standards organization. ANSI N42.23 defines a system in which the quality and traceability of service laboratory measurements can be demonstrated through reference (and monitoring) laboratories. The service (in this case the contracted) laboratory should analyze traceable reference performance testing materials to examine the bias and precision of an analytical methodology or an analyst. Traceable reference material, a sample of known analyte concentration, is prepared from standard reference material obtained from a national standards body (NIST in the United States) or derived reference material supplied by a

traceable radioactive source manufacturer (compliance with ANSI N42.22 for source manufacturers in the United States). Demonstration of measurement performance and traceability shall be conducted at an appropriate frequency.

E.7.5.3 Laboratory Evaluations Performed During the Contract Period

An audit before awarding a contract emphasizes an examination of availability of instruments, facilities, and the potential to handle the anticipated volume of work. This also includes recognizing that the proper personnel are in place to support the contract. After the award, a laboratory evaluation will place additional weight on how instruments and personnel are functioning on a daily basis. Thus, logbooks, charts, or other documentation that are produced as the work progresses are now examined. This type of evaluation during the contract period uses an approach that differs from the pre-award audit (Section E.5.5). The format and documentation for an on-site audit may differ from agency to agency. An agency may wish to examine the EPA forms (EPA, 1997) and either adopt these or modify them to accommodate radionuclide work that includes sample matrices other than water or additional nuclides not presently listed.

There are two types of evaluations or audits that can be performed during the life of a contract. The first involves agency personnel that visit the contractor's facilities. The second approach includes activities conducted by agency personnel without visiting the laboratory.

In the former case, agency personnel examine documentation at the laboratory, including each instrument's logbook which is used to record background values, or to ensure that QC charts are current. During this type of evaluation, the agency and contractor personnel have an opportunity to communicate face-to-face, which is a benefit to both parties when clarification or additional detail is needed. For example, this audit's goal essentially is to check the capability of the laboratory to perform the ongoing work according to the contract work. In this case, an auditor may request to see one or more data packages, and then follow the information described in each package—including such items as sample tracking and documentation concerning sample preparation and analysis—to verify that the laboratory is now accomplishing the work as described by the SOW and in conformance with the quality manual.

In the latter case, one conducts what might be called a *desk audit*, where agency personnel review the contract and examine records or documentation that have come in as part of the project's deliverables. For the most part, the agency should constantly be monitoring activities under the contract, and in this sense, a desk audit is a daily activity without a formal process being applied at any specific point in time. However, depending on the agency's practice, if on-site visits are not made, then a desk audit becomes the only means to track activities under the contract. One approach to a desk audit is thus a periodic review—for example, every 6 or 12 months—of QC records to track the laboratory's performance over that period of time. This allows the agency to determine if there are deviations, shifts, or other trends that appear over time.

Each evaluation presents an additional opportunity to monitor various laboratory parameters, such as turnaround time. This is most important in cases when samples contain radionuclides having short half lives. During an on-site evaluation, the agency is able to determine if additional emphasis is required to tighten the time frame between sample receipt and analysis. The personal interaction between agency and laboratory permits a constructive dialog and facilitates an understanding of the possible means to increase or maintain the efficiency when processing and analyzing samples at the contractor's facility.

E.8 Contract Completion

There are several general areas of concern at the close of a contract that may be addressed differently depending on the agency or nature of the project under a given contract. For example, agency personnel who monitor contracts will review invoices to be certain that work is complete and that the corresponding results are considered acceptable. Once such monitoring activity provides the proper verification that the work is complete, then the agency's financial office processes all related bills and makes final payment for the work.

The laboratory should send in final deliverables, including routine submissions of raw data or records, as is the practice under the contract. Also, when applicable, agency-owned equipment shared with the laboratory during the contract period will be returned. The disposition of samples still in storage at the contractor's facility and additional records or other raw data must be decided and specified. The agency may wish to receive all or part of these items—otherwise, disposal of sample materials and documents held by the contractor must be arranged.

In some cases, work under the contract may create conditions where more time is necessary to process samples that remain or to process additional work that arises during the latter part of the contract period. Depending on the agency, funding, nature of the project, or other factor, the contract may be extended for a period of time, which may vary from weeks to months. Otherwise, once the contract comes to a close, the work ceases.

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