

## Chapter 14

# Commercial Analytical Laboratories— Tendering, Selecting, Contracting and Managing Performance

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A total diet study (TDS) requires an analytical laboratory to determine the level of chemical compounds in the food samples collected. Some food regulatory agencies may have analytical laboratories directly associated with their organization, whereas others may not. In addition, for some specialized analyses, agencies may elect to outsource the analyses instead of developing their own in-house capabilities. For those regulatory agencies that use commercial analytical laboratory services, it is important to engage a competent laboratory for the food analyses prior to the sample collection stage of the TDS commencing. Such laboratory services may be located locally, in another part of the country or possibly in another country.

### Procurement Guidelines

To engage an analytical laboratory, it is essential to determine whether there are any procurement procedures which must be adhered to within the specific country. For example, in Australia, Food Standards Australia New Zealand (FSANZ) is a food regulatory agency that does not have an analytical laboratory directly associated with the organization. Therefore, in order to conduct a TDS, a laboratory, or in some cases, multiple laboratories, must be contracted to perform the analytical component of the project using a selection process that adheres to the Australian Commonwealth Procurement Guidelines [1]. Traditionally, the process by which analytical laboratories are engaged for the Australian TDS (ATDS) has been through a process that seeks a formal written proposal describing the laboratories analytical capability as well as a formal quotation of costs incurred to conduct the laboratory

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analyses. In recent years, FSANZ has used a widely advertised open competitive tender process through a *Panel of Analytical Laboratories*, which establishes specific *Deeds of Standing Offer* with each laboratory. The advantages of establishing a panel is that an analytical laboratory can be sourced directly from the panel to conduct analyses for the ATDS, following a request for quotation from the panel members. This expedites the procurement process, which is vital if analyses are required urgently, for example in the case of a food safety incident. Establishing a panel does not preclude FSANZ from using laboratories outside the panel, although a formal open competitive request for tender to the marketplace may need to be conducted depending on the value of the work. Therefore, this chapter will focus on the tender process in depth and subsequent contract development. Additional information on establishing a panel in Australia is available elsewhere [2].

## **Engaging an Analytical Laboratory**

To engage a laboratory to conduct analyses for a TDS, a formal selection process should be followed. However, the type and details of the process used may vary among countries. Therefore, the information herein is only as a guide and should not supersede any formal procurement guidelines within a specific country.

## **Tendering for a Total Diet Study**

### ***Preparing a Tender Document: What Should Be Included?***

Tender documents can generally be divided into three main sections, although other information may be necessary in individual countries according to their specific procurement guidelines:

1. Conditions of tender
2. Statement of requirement
3. Response format

A tender may also include the attachment of additional documents, such as a draft list of foods and analytes to be tested in the survey, a draft copy of the procedures manual (see Chap. 8 – Preparing a Procedures Manual for a Total Diet Study) including relevant preparation instructions for food samples and a copy of the draft proposed contract. This documentation aims to assist laboratories in understanding the scope and content of a TDS which may influence the laboratories' response to the tender.

## Conditions of the Tender

This part of the tender document includes the invitation to tender and a variety of procedural matters, such as where to direct enquiries regarding the tender, where to submit responses to tender documents and the process for managing late tender submissions. Also addressed in this section of the tender document is the responsibility of the tenderers, which may vary depending on the countries procurement requirements. It may address topics such as, who absorbs the costs of the response to the tender, declaration of potential or perceived conflicts of interest and other aspects such as the ownership of submitted tender documents.

## Statement of Requirement

TDSs are complex and therefore it is essential that the tender document clearly states the services that are required in a logical and comprehensive manner. This will assist the tenderers in preparing their responses to the request, which will enable a fair assessment and comparison of the costs/benefits presented by each tenderer. Provision of additional information on the background and purpose/objectives of the study are also useful to the prospective tenderers, as it provides context to the required services. If the major requirements are for analytical services and capacity to successfully conduct the large-scale survey within the expected timeframes, information on the prospective analytes and food samples, as well as any specific reporting requirements, should be detailed. Any other services that may also be required such as sample collection, sample preparation and sample compositing, as well as provision of sample containers for products that are purchased in an unsealed container (e.g. cold meats from a delicatessen), should also be listed.

Indicative timelines should also be provided in the tender document to give the tenderers an indication of the overall length of the project and the timeframes for the completion of each individual stage. It is important to include indicative timelines for the services requested in the tender document as it allows laboratories to consider other work commitments and to assess whether they have the capacity to participate in the large-scale study. For laboratories which may not have the capability to analyze for a specific analyte, it also provides an indication of the timeframe for when the development of the required analytical methodology will need to be completed. Alternatively, laboratories can be given the option to tender for only part of the analyses or subcontract those analyses to a secondary laboratory that can complete the analyses.

Specific information which should be sought in the tender includes:

- Analytical methodology for all proposed analytes.
- Level of detection that can be achieved and quantified for each analyte (i.e. Limit of Detection [LOD] and Limit of Quantification [LOQ] or Limits of Reporting [LOR]) (see Chap. 15 – Managing Concentration Data—Validation, Security, and Interpretation).

- Method validation including any accreditation.
- Quality assurance and quality control measures.
- Measurement uncertainty associated with the analyses and the basis for its determination.
- Sample collection and transportation capabilities.
- Quantity of sample required for analysis.
- Method of sample storage of both primary and composite samples.
- Management information such as:
  - Detailed timeline for the project
  - Details of current, pending and proposed accreditation
  - Details of relevant inter-laboratory proficiency testing recently undertaken
  - The contact details for a minimum of two referees

The expected outputs of the successful tenderer should also be detailed and may include:

- Coordinating the transport of samples to the laboratory
- Recording sample details on a spreadsheet or in a database
- Preparing primary and composite samples to a 'ready to eat' state
- Conducting analytical services
- Storing samples for a specified period of time
- Provision of analytical results as they become available, including detailed information regarding measurement uncertainty
- Submission of a final report of all sample analysis and product details

## **Response Format**

The tender documents may request that responses are submitted in a specific format. A uniform format with clear instructions should assist potential tenderers and reduce any uncertainty or ambiguity in preparing their responses. This approach will also assist the organization in the evaluation of responses to the tender.

In their response, the tenderer should demonstrate the company's ability to provide the requested services, fully address all specified criteria as well as provide any additional information requested. A failure to do so may compromise the quality of the tender and its further consideration in the evaluation process. This decision, however, is at the discretion of the organization seeking the required services.

## **Selecting a Tender**

### ***Evaluation Process***

Prior to conducting the tender evaluation process for the provision of analytical services for a TDS, it is important that compulsory and desirable criteria are used as a point of reference when evaluating each tender document and that

these are already established and approved by the organizations' legal team prior to advertising the tender. Similarly, it is recommended that a project team consisting of representatives from relevant areas of the organization be formed to evaluate each tender. Once all of the tender documents have been lodged by the specified closing date, the evaluation and selection process can commence.

### ***Compulsory Criteria***

As a first step, it is advised that each tender document is comprehensively cross-checked against each of the compulsory criteria. Examples of potential compulsory criteria that may be used as part of this process include:

- Lodgement of the tender by the specified closing date
- Declaration of any potential conflicts of interest
- Appropriate accreditation for performing the analytical services required
- Any issues in relation to confidentiality have been noted and explained
- Provision of business details, e.g. registered name, registered business number (if applicable), address, telephone and facsimile numbers and email address
- Contact details of an authorized business representative and their signature are provided
- Insurance details are provided, e.g. public liability and worker's compensation or similar
- A business continuity plan in place that guarantees full provision of required analytical services

It is at this stage, and at the discretion of the tender evaluation team, that any tender documents, which are considered to be non-compliant with the compulsory criteria, may be removed and not progressed for further evaluation.

### ***Desirable Criteria and Ranking***

Following the initial evaluation of tender documents against the compulsory criteria, the documents may be evaluated against a list of desirable criteria with an assigned weighting in order to further facilitate the short listing of potential tenderers. The weighting assigned is not generic but dependent on the specific project and is at the discretion of the organization. Examples of desirable criteria used as part of the tender evaluation process may include:

- Demonstrated ability to meet the agency's statement of requirements for conducting a TDS (e.g. a thorough description of similar and/or recent analytical services performed by the tenderer)
- Evidence indicating a clear understanding of the food regulatory environment and pertinent legislation, where applicable

- Demonstrated ability of personnel who will be assigned to work on the analysis (e.g. provision of curriculum vitae outlining the skills and responsibilities of each person for performing the required analytical services)
- A comprehensive summary that demonstrates the tenderers ability to manage a large and complex project and to deliver successful outcomes within specified timelines

Once all of the tender documents have been evaluated against the desirable criteria, a ranking for each can be calculated based on the weightings and a short list generated. For example, achieving the requirements of the tender may be assigned a weighting of 30 %, the tenderer's capacity and infrastructure 30 % and value for money and potential risk 40 %. Weightings can be modified against the criteria in the "Request for Tender", if desired.

### ***Assessment of Value for Money and Risk***

The remaining short listed tender documents should be evaluated for value for money against relevant procurement policies where applicable. For example, when FSANZ is evaluating tender documents for engaging a laboratory for the analytical component of the ATDS, the process followed must be consistent with procurement principles around value for money as stipulated in the Australian Commonwealth Procurement Guidelines [1].

In terms of evaluating the overall potential risk to the agency in contracting any one of the short listed tenderers, it is advised that an assessment be conducted on each to address the following fundamental elements:

- Financial stability
- Accountability and transparency
- Security
- Flexibility

Following this assessment, an overall ranking can be assigned to each of the short listed tenderers. This process will assist the tender evaluation team in selecting the successful tenderer who will be awarded the contract for the TDS.

### **Establishing the Analytical Contract**

Establishing a contract between the selected tenderer and the organization conducting the TDS is essential in ensuring complete understanding of the expectations of the services required. The contract (or letter of agreement or memorandum of understanding) is a legally binding agreement between the selected analytical

**Table 14.1** An example of a payment schedule for a TDS

Milestone	Detail	Fee amount <sup>a</sup>
1	On execution of the contract	x % of total fees payable
2	On completion of all analysis for the first sampling period and presentation of interim data report in electronic and hard data copies to the organization	y % of total fees payable
3	On completion of all analysis and presentation of the final data report in electronic and hard data copies and acceptance of the final report by the organization	The remaining fees payable

<sup>a</sup>Where 'x & y' are the numerical value determined by the organization seeking the analytical services

laboratory and the organization conducting the TDS, which outlines all agreed services and associated costs. The agreed services may not be limited to sample analysis and may also include the following:

- Coordinating sample transportation
- Provision of portable food coolers (chilly bins) and cold bricks
- Sample preparation and compositing
- Sample storage for a specified period of time following the completion of the project

The agreed LOD and LOQ or LOR for each analyte in the various food matrices should also be listed. The agreed cost for all services and a final overall cost for the entire service should be detailed. An agreed payment schedule, including specific details around what stage in the project payments will be made, should be outlined. As the TDS is a large-scale survey which can be conducted over a long period of time, it may be worthwhile scheduling payments throughout the course of the project when significant milestones have been reached. The schedule would be dependent on the range of services provided by the analytical laboratory. However a simplified example is shown in Table 14.1.

The example in Table 14.1 may be even more specific where required with the payments broken down further. For example, milestone 2 could be specified payments to include (1) completion of sample coordination, (2) sample preparation and (3) compositing.

The analytical contract should also include the specific details that the organization requires in each invoice to make the relevant payments for each milestone. Information such as, 'Title of Agreed Services', the name of the project manager and an itemized list of fees and expenses should be included. A timeframe for payment following receipt of the invoice by the organization should also be included so the laboratory can account for when payments will be received.

## Managing Performance

The TDS may require the analytical laboratory to be engaged for up to 2 years, depending on the sampling schedule, number of samples and timeframe for analysis. Therefore, it is important to maintain regular contact with the laboratory to monitor the progress of the study, ensure interactions between the sampling officers and laboratory is occurring, and to provide regular feedback to manage the laboratory's performance. Regular contact could be made at significant stages within the project, such as dispatch of transport containers, completion of sampling, receipt of samples at the laboratory and completion of analytical results. If more than one sampling period is required, it is useful to contact the laboratory prior to subsequent sampling periods to critically assess how the previous sampling period was performed and determine whether there is anything that could be incorporated into the next period to improve the study. Alternatively, it may be useful to establish a regular meeting, for example monthly, to discuss any issues that may have arisen. Frequent contact between the project manager and the laboratory builds and maintains communication and encourages contact in the event of any issues arising which require prompt resolution.

## Summary

The planning and management of the analytical component of a TDS is a comprehensive process. Therefore, thorough consideration should be given to the analytical services required to successfully conduct the study and to ensure that these are documented in a clear, detailed and logical manner. It is important that any country's specific procurement guidelines as well as organization specific guidelines are adhered to throughout the procurement process from the release of request for tender, to evaluation, selection and contracting of the analytical laboratory. In addition, effectively managing the performance of the contracted analytical laboratory for the duration of the analytical component is critical to the success of the study. Maintaining regular contact with the laboratory is recommended in order to foster a positive and productive working relationship that achieves agreed outputs.

## References

1. Commonwealth of Australia (2008) Commonwealth procurement guidelines. Department of Finance and Deregulation, Canberra. <http://www.finance.gov.au/publications/fmg-series/docs/CPGs-2008.pdf>. Accessed on 16 Sept 2009
2. Commonwealth of Australia (2007) Establishing and using panels. Department of Finance and Deregulation, Canberra. <http://www.finance.gov.au/archive/archive-of-publications/good-procurement-practice/docs/Book4.pdf>. Accessed 25 Jan 2012