GL 20 Review of Requests and Tenders Document ID: 1421

Revision: 11

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Approved by Director: Dr. Guy Vallaro

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A. <u>PURPOSE</u>:

Customer service is of utmost importance to the Division of Scientific Services; as such, requests, contracts and tenders are reviewed to ensure continued compliance with their requirements. The purpose of this procedure is to describe and define the process by which such review occurs.

B. RESPONSIBILITY:

- 1. Managers: Responsible to provide direction to subordinate staff under their purview as indicated by the organization chart.
- 2. Supervisors: Responsible to provide supervision to subordinate staff under their purview as indicated by the organization chart.
- 3. FSE2: responsible as a working lead to subordinate staff as indicated on the organizational chart.
- 4. FSE1 and Lab Assistants: Responsible to adhere to this procedure as it pertains to their Unit.
- 5. ECO: Responsible to adhere to this procedure as it pertains to their Unit.
- 6. Support Personnel (however titled): Responsible to adhere to this procedure as it pertains to their Unit.

C. **DEFINITIONS**:

1. Major Deviation:

- a. (To a method or process): To include work performed by the laboratory that is not covered under a current procedure or to include a change to a DSS procedure that is significant enough to require verification of the validity of the change.
- b. (To a Contract): To include changes to a customer contract where evidence is submitted for a specific type of work and the DSS determines, based on review of the evidence, that additional work in a different discipline is indicated or where the DSS needs to use non-standard testing methods.
- 2. <u>Minor Deviation</u>: to include work performed by the laboratory that is covered by a procedure where a slight change is required which does not scientifically invalidate the method.

D. **PROCEDURE**:

1. <u>Contracts/Tenders/Requests</u>:

- a. As part of the annual Management System Review the customer contract will be reviewed to determine if it still meets the needs of the customers. Each Unit is responsible for contractual obligations applicable to that Unit, under the general authority and responsibility of the Director.
- b. If there are any specialized contracts, these will be similarly reviewed to ensure the customer's needs are continued to be met.

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c. If contracts for outsourcing of testing (sub-contracting) are obtained, the Quality Section will maintain a list of the acceptable contracted vendors. The contracts will be reviewed annually. This annual review can be performed during the Management System Review but may occur earlier within the year based on the needs of the contract.

2. Evidence Submission to the Laboratories:

a. When an agency/customer submits evidence to the Division for examination a Request for Analysis form is used. This form is reviewed for appropriateness following Evidence Receiving SOPs. Requested analysis will be reviewed to ensure it is appropriate to the analysis the DSS offers.

Note: When iPrelog is used a Request For Analysis (RFA) form is not required and the iPrelog receipt can be used in its place.

- b. When the evidence is entered into JusticeTrax, a receipt is generated. The receipt lists what was submitted and has the contract between the Division and the submitting agency printed on it.
- c. Each specific Unit shall, as a function of the contractual agreement with the customer, specify and use appropriate procedures which meet the needs of the customer and which are appropriate for the examination/testing required.
- d. If a request is found to be inappropriate, such as the requested testing is outdated, then the customer will be contacted to clarify what is needed. This communication will be documented in the case file.
- e. The contract between the Division and submitting agency states:

Agencies submitting evidence to the Division of Scientific Services for specific analysis agree to allow the Division to determine the appropriate methodology for the evidence submitted and agree to the use of either handwritten or electronic signatures on Division reports. Agencies also agree to a simplified report where the dates of performance of laboratory activity will not be on the reports but available upon request. Descriptions of analyses offered by the Division are detailed on our website. If the Division needs to deviate from standard test methodologies you or your agency will be contacted prior to the analysis being performed. The Division reserves the right to use contract laboratories to perform case analysis as needed. This contract serves to inform you as the client of this potential event. In the event a contract laboratory is used the name and address of the contract laboratory will be stated on the laboratory report to the submitting agency. Any concerns or specific requests about the required testing can be discussed with the section Deputy Director or Director prior to case analysis.

f. By submitting evidence to the DSS the customer agrees to the contract as printed on the evidence receipt.

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g. The DSS's agreement with the customer includes the capability and resources to meet the requirement of the contract.

- h. If an amendment to the contract is required at any stage within the DSS, the customer will be contacted, the amended contract will be documented, the amended contract will be reviewed and appropriate personnel will be notified.
- i. The evidence receipt will be maintained in the administrative case file maintained by the Evidence Receiving Unit. Alternatively it may be maintained electronically as part of the case records in LIMS.
- j. When an agency has a Memorandum of Understanding (MOU) with the DSS this MOU will supersede the above contract or work in conjunction with that contract based on the details of the MOU.
 - i. For these cases, evidence receipts may not be generated; other methods of documenting the evidence transfer from the customer to the laboratory may be acceptable.
- 3. <u>Deviations/Changes to Contracts (before or after work begins):</u>
 - a. When a major deviation to a contract must be made, it must be approved by the customer prior to the work being performed. Additionally all major deviations will be approved by the Director prior to implementation. Customer approval can be obtained verbally, however the information must be documented in the case file. This should include a description of the change, the name of the person (customer) accepting the change, the date and the DSS employee that contacted the customer.
 - b. When the DSS proposes a deviation, the deviation must be such that it will not impact the integrity of the casework/validity of the results.
 - i. A major deviation would include the use of a non-standard method or anything that causes work to be performed other than that in which the case was originally submitted for.
 - Example: A case was submitted for FB/DNA analysis; during the initial examination materials having the appearance of drugs are found. The customer would be contacted to determine if they wanted drug analysis performed on the found materials. Although this is not a deviation from testing methods offered by the DSS it is a deviation from the RFA.
 - ii. A major deviation would include applying a method in a manner that it was not initially intended or performing work that is outside of the normal scope of testing for the DSS.
 - iii. Minor deviations do not require the customer to be contacted for approval. Minor deviations still require approval of the Director as documented in a Qualtrax 'Deviation Request' workflow.
 - (a) Examples of Minor deviations:

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(i) Choice of solvent for an established method, if it is documented such as in a reference that the other solvent is a better choice for the specific condition/item of the case.

- (ii) Sending evidence to a contract laboratory, if the contract vendor is analyzing the case materials for the same type of analysis in which it was submitted to the DSS for (i.e. outsourced case work). Note that outsourcing of casework does not require approval from the Director via a 'Deviation Request' workflow in Oualtrax.
- (iii)Applying a DSS method to a different sample matrices than originally intended; this may be as simple as a different collection media such as type of collection device.
- iv. If it is unclear if a change falls under a major or minor deviation the Assistant Director or Director will work with the Quality Manager to determine the level of deviation. In the DNA Unit the Technical Leader will be consulted.
- c. Work where the DSS is acting solely as an agent for the customer is not seen as a deviation. This may include shipping of evidence on behalf of the customer, to a 3rd party laboratory, where a method not performed by the DSS is required (examples: paint analysis, genealogy for DNA cases or others).
 - (a) In these cases, the DSS is not creating a report based on the results provided by the 3rd party laboratory.
 - (b) In these cases, the case record will contain any communication with the customer concerning the need to forward the evidence to another laboratory.
- d. Deviation requests are entered into Qualtrax using the Deviation Request workflow. This is used to document the internal approval of a deviation. Approval must be obtained via the completed workflow prior to performing the deviation.
 - i. The Deviation workflow should be printed and placed in the related case file(s), attached to the case(s) in LIMS or a notation will be added to the casefile(s) where the deviation request workflow ID number is documented.
- e. Administrative Deviations: Deviations may also be used for changes to administrative type procedures. The Qualtrax workflow will be used for these also. There is no customer approval needed for these since they generally are not case specific.
 - i. Example: a deviation may be a needed due to shifting the dates of a scheduled maintenance past the allowable date range or performing an audit in a manner not prescribed in the GL SOP or other change from an administrative procedure.
- 4. Contact with Customers:

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a. Any employee who is contacted by or contacts a customer concerning changes to a contract of a case (whether verbal or written) must note the following in the case file:

- i. date of contact
- ii. the name of the customer
- iii. contact information
- iv. brief overview of the discussion
- v. what was agreed to
- b. These records will be maintained in the case file (this may be paper or as part of the case in LIMS) for the life of the case file. If the change to the contract is documented as a major change, a copy of the information will be maintained electronically within the case in LIMS.

