Model Request for Proposals for Equine Drug Testing Laboratory

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The aim of this document is to facilitate the selection of a testing laboratory that 1) provides analytic services that meet or exceed industry standards; and, 2) represents the best value to the regulatory agency in supporting the enforcement of its regulations.

> **Note:** RMTC laboratory accreditation informs the regulatory agency that a laboratory has the requisite analytic capabilities; it does not establish or ensure performance standards with respect to the analysis of regulatory agency samples. It is therefore the responsibility of the regulatory agency to unequivocally require the laboratory to perform to industry standards when analyzing its samples. To do otherwise subverts the goal of uniformity in medication regulation and creates the 'illusion of integrity,' rather than the application of fair and consistent testing across all racing jurisdictions.

The process of laboratory selection calls for thorough and aggressive due diligence by the regulatory agency. This can be immensely problematic given that few regulators have the technical knowledge, nor the time and/or resources to develop adequate knowledge to critically evaluate a candidate laboratory. This document provides, in addition to the requirements to be included in a model Request For Proposals (RFP), explanation and justification for each requirement in order that agency officials understand the RFP they release, and have confidence that the document accurately represents the agency's needs. This information may also be useful in defending RFP criteria and testing specifications to other state agencies that may be involved in the laboratory procurement process.

The evaluation should reconcile the needs of the regulatory agency, the expectations of the industry, and available funding. The lowest price does not necessarily represent the best value. Scoring that is based solely on price can undermine a responding laboratory's ability to offer testing to industry standards and public expectations, UNLESS, the regulatory agency's RFP is meticulous in defining its testing and laboratory support requirements.

Candidate laboratories must be Racing Medication Testing Consortium (RMTC) accredited and thus possess comparable analytic capabilities. Therefore, pricing offered that is substantially lower than that in other responses should be closely scrutinized. Cost cutting measures (declared or hidden) are likely to affect the quality of the testing performed.

For the regulatory agency with substantial budgetary constraints, it may be necessary to contemplate testing fewer samples in order to subject them to analysis consistent with industry expectations. In all cases, the submission of paired (blood and urine) post-race samples is critical to the laboratory's ability to support its client's regulations. A decision to constrain cost by submitting only blood samples

severely limits the number of substances that the laboratory can detect. Uniform rules are uniform only to the extent that they are enforced consistently.

It is, in fact, preferable to define the agency's requirements and solicit pricing on a per-sample basis—at which time the agency can decide how many samples it will test. The alternative—identifying the total sum allocated for testing and the number tests to be performed, and then soliciting pricing—may actually require laboratories to offer testing below established standards, in order to function within the other, fixed variables (budget and number of tests).

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I. Background information provided by the issuing agency

The solicitation should provide the following information:

1. Number of race days (at each track, if multiple racetracks are involved)

2. Racing calendar, including post times (such that the responding laboratory can identify prospective shipping schedules)

3. Copy of the current medication regulations, (including information relevant to filed or pending regulation changes)

4. The address of each racetrack from which samples will be submitted to the laboratory, the name and phone number of the agency's contact for each racetrack

5. Description of previous drug testing services/activity including:
    1. number of samples (post-race, post-work, TCO_2, out of competition [blood/urine/hair], investigative [e.g. bisphosphonates] or other [e.g. necropsy blood/urine/bone/aqueous humor samples]) submitted during the previous 2 calendar years;
    2. frequency of 'suspicious' samples requiring confirmatory analysis;
    3. list of reports of finding issued by the agency's official laboratory for the preceding calendar year
6. Description and amount of other work performed by the official laboratory within the preceding 12-month period (e.g. analysis of unknowns/confiscated substances/syringe residues, testing performed for non-regulatory/intelligence gathering purposes)

7. Estimate of the number of serum and urine samples (including post-work) to be tested in a 12-month period; provide explanation for any change in sample numbers that is greater than 10% relative to the previous 12-month period.

8. Estimate the number of hair samples to be tested in a 12-month period and list substances required to be included in analysis (e.g. anabolic steroids, clenbuterol, albuterol).

9. Estimate of the number of TCO_2 samples to be tested in a 12-month period; provide explanation for any change in sample numbers that is greater than 10% relative to the previous 12-month period.

10. Approximate number of human samples to be tested. List substances required to be included in analysis.

11. A description of the sample shipment schedule used in the previous 12 month period.

Comment: *It is strongly recommended that all official post-race samples be subjected to the same scope of analysis. It is difficult to credibly justify a lesser scope of testing for non-stakes races. Wagering integrity spans all classes of racing, and the public is unlikely to accept that through its testing program the regulatory agency is tolerant of racing at lower levels importance being impacted by the use of medication (regulated or prohibited) in a way that is not permitted at other classes of racing. Industry standards for screening analysis have evolved from individual ELISA test kits that were, out of necessity, rotated. Instrumental screening is now the basis for drug testing programs allowing for the same expansive scope of analysis to be applied to all samples. This renders the current Thoroughbred Owners and Breeders' Association American Graded Stakes (TOBA-AGS) Committee requirements, that were established for an ELISA-based program, obsolete. Regulatory agencies should not need to require enhanced testing for Graded Stakes races, nor should there be added expense for the analysis of those samples.*

II. Requirements for sample collection/processing/shipment

1a. The laboratory shall provide to the Commission staff all items necessary to collect, label, process, store, and ship samples, inclusive of: blood collection tubes, blood collection needles, lidded urine collection cups of sufficient size to collect the required sample volume as established by the laboratory, primary and split sample urine specimen containers with screw caps, urine collection sticks, non-sterile exam gloves, sequentially numbered barcoded sample ID tags, tamper-proof security tape, centrifuge, refrigerator, freezer, chain of custody documents, shipping containers, security locks, coolants, padding/absorbent fill, secondary watertight receptacles, and shipping labels. The laboratory shall bear all costs associated with the shipment and delivery of supplies to Commission staff.

In its Response the laboratory shall provide samples, or photographs and descriptions of materials and equipment described above.

OR

1b. The laboratory shall provide to the Commission staff clear and detailed specifications and sources for all items necessary to collect, label, process, store, and ship samples inclusive of: blood collection tubes, blood collection needles, lidded urine collection cups, primary and split sample urine specimen containers with screw caps, urine collection sticks, non-sterile exam gloves, sequentially numbered barcoded sample ID tags, tamper-proof security tape, centrifuge, refrigerator, freezer, chain of custody documents, shipping containers, security locks, coolants, padding/absorbent fill, and secondary watertight receptacles.

Comments: *Rather than requiring the laboratory to supply the above-described materials the regulatory agency may elect to purchase some or all through government contract in order to reduce costs.*

Regulatory agencies should be aware that a requirement for the responding laboratory to provide refrigerators, freezers, centrifuges or other Test Barn hardware, will add to the overall cost of the contract. Local purchase of refrigerators, freezers, and centrifuges may afford a more timely response should repair or service be required. (A service contract is recommended at the time of purchase.)
To the extent that the laboratory is required by the regulatory authority to supply sampling materials, those materials should only be used for the purpose of testing of samples by the laboratory. If the regulatory authority elects to collect samples for other purposes, it should expect to pay for those materials, and should request pricing from the laboratory in the RFP.

At the end of the day, there should be a clear understanding of which Test Barn supplies and equipment will be provided by the laboratory and which by the regulatory authority. For the purpose of comparing RFP responses, the laboratory's obligations should be included as requirements in the RFP rather than negotiated after the fact.

Sample Collection Supplies Described

1. Collection materials
    1. Blood collection tubes, size (volume) and type (i.e. serum separator, EDTA, heparin, sodium citrate) to be determined by
        1. the testing methodology employed by the laboratory, and
        2. the regulatory agency's statutes and/or regulations (i.e. If a substance is regulated by a threshold in plasma, anticoagulant tubes must be utilized. The analysis of serum when a

regulation specifies a threshold in plasma may prove problematic when prosecuting cases.)

2. Collection needle gauge and length are best determined by the preference of those performing phlebotomy in the Test Barn. The laboratory shall be notified of the agency's needle preferences. (Small bore needles [≥21-gauge] may result both longer fill times and erythrolysis (destruction of red blood cells) which can impact certain testing methods. Large bore [≤18-gauge] needles increase the risk of hematoma post-collection.) It is advisable to maintain a small inventory of silicone-free collection needles in the event a horse with a history of adverse reaction is presented for testing.
3. Urine collection cups (minimum6 oz.) should be lidded and bear a tamper evident security seal (that can be verified as intact before the lid is removed to perform sample collection).
4. Urine primary specimen cups (20-120 ml depending on the laboratory's urine volume requirements) with screw caps
5. Urine split sample specimen cups (20-120 ml depending on the laboratory's urine volume requirements and the regulatory agency's storage capacity) with screw caps
6. Urine collection sticks
7. Non-sterile latex-free exam gloves (to be worn by individuals performing urine collection)
8. Evidence tape (for sealing stoppered ends of blood tubes and lids of primary and split urine containers.

1. Sample ID tags and chain of custody materials
    1. Sample ID tags
        1. adhesive backed (peel and stick) sequentially numbered, barcoded labels
        2. sufficient number of labels to identify all samples (blood, urine and hair) collected on a routine basis
        3. information capture relevant to the specific needs of the regulatory authority (i.e. track, race, date, horse, trainer, horse's medication status, gender, claimed horse, etc.)
        4. Sample inventory form (copy retained in Test Barn, copy to accompany shipment.

2a. The laboratory shall provide on-site training for Commission staff in the collection, labeling, processing, management, packaging, and shipment of official samples.

OR

2b. The laboratory shall provide training materials for Commission staff on the collection, labeling, processing, management, packaging, and shipment of official samples. The laboratory shall provide a copy of proposed training materials in its Response.

Comment: *On-site training represents added expense, but also provides the opportunity for an audit of test barn protocols. If an on-site audit by laboratory personnel is not possible, the regulatory authority should request the laboratory provide guidance on self-audits and quality control assessments to be performed on a regular basis. The distribution of training manuals by the laboratory represents a reduced-cost option. Either way, there should be a clear understanding between the laboratory and the Commission's Test Barn staff for all procedures related to sample collection, labeling, processing, packaging and shipping. How samples are managed prior to their arrival at the laboratory has a direct impact on the quality of the ensuing analysis.*

III. Test Barn supply inventory management

If 1a. (or modification thereof) is utilized--

3. The laboratory shall deliver to the address provided by the Commission an inventory of materials (as described in section 1) no less than 24 hours prior to the beginning of each race meeting. Commission staff shall monitor depletion of the inventory and submit requests to the laboratory for replenishment two weeks prior to critical need, or at mutually agreed, predetermined intervals.

IV. Shipping

4a. The laboratory shall provide clear instructions for packaging of samples such that samples are shipped in accordance with applicable government, International Air Transport Association (IATA) and International Civil Aviation Organization (ICAO) regulations. The laboratory shall provide chain of custody materials.

The laboratory shall bear all expense associated with priority overnight shipment of samples by commercial shipper or by bonded courier (next day delivery by 10:30 a.m.) and standard delivery return of empty coolers to Commission staff to an address provided by the Commission. The laboratory

shall be responsible for tracking shipments and identifying and remediating delays or diverted shipments. The regulatory agency shall notify the laboratory when samples ship and provide a tracking number.

The laboratory shall appoint a key contact person for the Commission for all matters related to sample shipping. The key contact person shall be accessible on days during which live racing takes place, inclusive of weekends and holidays.

OR

4b. The laboratory shall provide clear instructions for packaging of samples such that samples are shipped in accordance with applicable government, International Air Transport Association (IATA) and International Civil Aviation Organization (ICAO) regulations.

The laboratory shall provide chain of custody materials.

The Commission shall bear all expense associated with priority overnight shipment of samples by commercial shipper or by bonded courier (next day delivery by 10:30 a.m.) and standard delivery return of empty coolers to Commission staff. The Commission shall be responsible for tracking shipments and identifying and remediating delays or diverted shipments and performing the necessary notifications to the laboratory.

The laboratory shall provide detailed specifications for shipping containers, packing materials, absorbent fill, coolants, and secondary watertight receptacles.

Comment: *The regulatory agency may expect that shipment of single race day sample sets will result in increased cost when compared to batch shipment of several days' samples. Scheduling of shipments must take into consideration the racing calendar and the laboratory's hours of accession. Regulatory agencies may expect increased shipping costs (and possibly increased laboratory costs) when sample deliveries are scheduled for weekends or holidays.*

Will the regulatory agency retain split samples or will they be transported with the primary samples to the laboratory? If the laboratory is expected to inventory and warehouse split samples, the regulatory agency should anticipate additional expense that will vary depending upon the duration of the stipulated retention period of the split samples. Also, if the laboratory is expected to warehouse the split samples, the RFP should clearly indicate what party (laboratory, regulatory agency, or trainer) is authorized to release them to the split sample laboratory and who is responsible for

costs associated with shipment of a split sample to a reference laboratory. The RFP should define what communications are permitted with individuals other than representatives of the commission. For matters related to split sample analysis, the commission may require its representative to be present on all calls.

In Section I, Background Information, the regulatory agency should define the desired sample shipping schedule, and clarify what samples (primary +/- split) that the laboratory will be expected to receive, inventory, and manage.

Shipping materials described:

2. Containers
    1. Insulated cooler with rigid sides
    2. Size to be determined by number of samples (number of race days) and size of sample containers to be shipped
    3. Lighter weight coolers are preferable as shipping rates are weight dependent
    4. Must have lockable hasp, or be modified in order to accommodate security lock
3. Locks/security
    1. Single-use, uniquely numbered, tamper-proof devices
    2. Keyed padlocks may be used, but alone do not represent a best practice
4. Coolants
5. Padding/absorbent fill
6. Secondary watertight receptacle

V. Laboratory Personnel

5. The Laboratory Director and senior chemists shall be professional members in good standing of the Association of Racing Chemists (AORC) and have, relevant to their responsibilities, a scientific degree in one or more of the following fields: chemistry, pharmacology, toxicology, veterinary science, or pharmaceutical science.

The responding laboratory shall provide relevant biographical information (education, degrees achieved, experience, scientific publications, ongoing research, and industry relations/outreach) for the laboratory director, senior chemists, and data review analysts.

The responding laboratory shall provide an organizational chart and job descriptions for all employees performing contracted services relevant to the regulatory agency's samples.

The responding laboratory shall provide documentation of the training program for all employees performing contract services relevant to the regulatory agency's samples. This documentation shall include a description of ongoing proficiency testing and performance review—including a summary of internal proficiency performance, any deficiencies noted, corrective action plans (CAPAs) applied, and CAPAs outcomes.

The laboratory shall identify and provide contact information for a Key Contact Person for the regulatory agency. This individual shall be available during standard business hours as well as evenings, weekends, and holidays. The laboratory shall also identify and provide contact information for a designated back-up contact for the Commission.

The laboratory shall describe its succession plan for key laboratory staff.

Unscheduled changes in key laboratory staff (i.e., laboratory director, laboratory manager, commission key contact, quality control officer, and senior chemist) determined to be unacceptable by the regulatory agency may result in early termination of the contract.

Comment: *Only qualified personnel should be in contact with its official samples, and the laboratory, as a routine practice, should monitor and evaluate individual performance. The laboratory should have clear criteria for the amount of experience and proficiency required at each level of interaction with the agency's samples. The laboratory must document that it employs a sufficient number of qualified personnel who will be assigned to the agency's samples such that turn-around-time requirements can be expected to be reliably met.*

It is important that the laboratory has a succession plan in place. Illness or accident can occur without warning, and a lack of succession plan could render the laboratory incapable of meeting its contractual obligations for an unspecified period of time.

VI. Laboratory Facilities

6. The laboratory shall demonstrate that its facilities are secure from access by unauthorized individuals and that sample-handling areas are user-specific and accessible only by manual key or electronic/digitized device.

The laboratory facility shall affirm that is has a power-failure notification system and an alternative power source to prevent compromise of samples in the event of a power outage.

The laboratory shall demonstrate that it has adequate laboratory work space and storage capabilities to meet the anticipated sample load to be submitted by the regulatory agency and the laboratory's other clients.

The laboratory shall provide documentation that its facility is OSHA, ISO 17025, and Racing Medication and Testing Consortium (RMTC) compliant; and local code compliant.

Comment: *Requirements defined in Section VI can be considered fulfilled if the laboratory has received full RMTC accreditation. (See below)*

VII. Laboratory Accreditation

7. The laboratory shall provide documentation that it has ISO 17025 and full RMTC accreditation, and that its accreditation is in good standing.

The laboratory shall disclose any deficiencies noted on the most recent accreditation (or re-accreditation) site inspection and provide documentation that said deficiencies have been remedied.

The laboratory shall disclose any deficiencies and corrective action plans in the previous 4 rounds of single-blind RMTC EQAP samples.

The laboratory shall disclose if its accreditation has ever been suspended, revoked, or otherwise sanctioned. The laboratory shall provide the details of any sanction and its resolution.

Comments: *ISO 17025 accreditation does not address a laboratory's testing sensitivity or require specific analytic methods. This accreditation establishes that the laboratory can perform the work that it says it can, and that it can provide consistent results—either through the repeat analysis of a single sample, or the analysis of multiple samples over time. ISO 17025 accreditation alone should not be inferred to mean that a laboratory has the capabilities required to provide analytic support to the agency's medication regulations.*
RMTC accreditation, through its external quality assurance program, is intended to establish that the laboratory has the analytic methods in place to detect substances of regulatory interest at relevant concentrations. Unfortunately, a regulatory agency has the ability to require that its laboratory perform its contractual work at substantially lower standards—often as a cost saving measure—and constrain the laboratory from doing the work of which it is capable. Such a decision negates all value associated with laboratory accreditation and prevents the agency from fulfilling its regulatory mandates. It is the responsibility of the issuing regulatory agency to

require that testing be performed to the current industry standards, such that uniform rules can be supported by uniform testing.

VIII. Quality Control and Quality Assurance

8. The laboratory shall participate in AORC and RMTC external quality assurance programs (EQAP). The results of the laboratory's analysis of single- or double-blinded proficiency samples shall be disclosed to the regulatory agency within 30 days of its receipt of the EQAP's report. For any testing deficiencies, the laboratory shall provide documentation of the correction plan to be implemented, and a timeline for implementation. For any other EQAP(s) in which the laboratory participates, the laboratory shall provide all results, and corrective action plans as required. The laboratory may not substitute other EQAPs for the AORC and/or RMTC programs.

The laboratory shall routinely perform analysis of internal blind samples of substances of regulatory interest at relevant concentrations. The laboratory shall notify the regulatory agency within 5 business days of a failed analysis, and provide a corrective action plan (and timeline) for remedying the deficiency. The laboratory shall provide the regulatory agency with quarterly reports of EQAP and Internal Blind sample analysis, inclusive of the analytes detected.

The laboratory shall provide the preceding 90 day's history of internal blind sample analysis in its Response.

The laboratory shall provide a full description of its internal quality control measures in its Response and affirm that it has a designated, qualified Quality Assurance/Quality Control officer having the requisite authority to remedy deficiencies identified.

Comment: *For a laboratory to maintain its accreditation it is required to participate in EQAP. A regulator is rarely in the position to accurately assess a laboratory's technical capabilities or performance. However, the regulatory agency should be very interested in how many internal blind samples are analyzed, how many external quality assurance samples are analyzed, and how the laboratory performed on those samples. Other than split sample analysis, this is the best available audit of the laboratory's performance. The client should expect a strong commitment from the laboratory with respect to quality, and the willingness to endure scrutiny of its Quality Control and Quality Assurance programs. A laboratory's reluctance to disclose QA/QC programs and performance should be a red flag to a potential client.*

IX. Standard Operating Procedures

9. The laboratory shall affirm that it has Standard Operating Procedures (SOPs) for all processes and methods. SOP's should be, where applicable, based upon methods that will detect substances at or below the regulatory thresholds required by the agency's regulations. The laboratory shall archive copies of retired SOPs in such a manner that the procedures that were used to test each specific sample can be identified. The SOPs shall be accessible to laboratory staff. SOPs shall be reviewed and updated, as warranted, on a regular basis.

Comment: *Historically, some regulatory agencies have requested copies of the responding laboratory's SOP manuals. This is problematic in that the contents are proprietary, but may then be subjected to open records laws after being transferred to the soliciting agency. ISO 17025 accreditation requires that the laboratory have SOPs, that the SOPs are utilized, and appropriately maintained. ISO 17025 accreditation site inspections include review of SOPs by qualified individuals. The review of an SOP by unqualified individuals (i.e. regulatory agency personnel) does not add value to the responding laboratory's application.*

X. Sample Management / Sample Retention

10. The laboratory shall have a Laboratory Information Management System (LIMS) in which all interactions with each sample are documented--from accession through the issuance of a final report, and until such time as the sample undergoes disposal.

All samples shall be assigned unique laboratory identification numbers. Assignment of internal laboratory identification numbers shall be performed by sample accession personnel in a dedicated sample receiving area that is segregated from areas where analyses are performed or drug reference standards are used.

Prior to the initiation of any analysis, samples and their corresponding documents shall be inspected with any irregularities promptly reported to the regulatory agency. The regulatory agency shall then provide the laboratory guidance with respect to the analysis of the affected sample.

With the exception of TCO_2 analysis, all other analyses shall be initiated within 24 hours of the samples' arrival at the laboratory. Analysis of TCO_2 samples shall be initiated promptly upon the samples' arrival at the laboratory. TCO_2 testing shall not be performed on samples that were collected 120 or more hours prior to analysis. The laboratory shall promptly notify the regulatory agency when testing is aborted due to sample age.

From time of accession through the issuance of a final report, all primary blood samples shall be retained in a secured refrigerator and all primary urine samples retained in a secured freezer. Long-term storage freezers shall likewise be secured and accessible only to authorized laboratory personnel.

Negative (passed) samples shall be retained in a refrigerated (blood) or frozen (urine) condition for a period of _____(days/months).

Suspicious, but subsequently passed, samples (blood and urine) shall be retained in a frozen condition for a period of _____(months).

Positive (failed) samples (blood and urine) shall be retained in a frozen condition (-80° C) for _____(months/years). The regulatory agency must authorize the disposal of positive (failed) samples, regardless of the designated retention interval.

AND

10a. At the end of the specified retention period, the laboratory shall automatically dispose of the passed and suspicious samples

OR

10 b. At the end of the specified retention period, the regulatory agency will, upon request by the laboratory, authorize disposal of the passed and suspicious samples.

If the laboratory is to inventory and retain split samples….

10.1 Split samples (blood and urine) shall be retained in a frozen condition (-80° C) for _____(months/years). The regulatory agency must authorize the disposal of split samples at the end of the designated retention interval.

If the laboratory is to inventory and retain untested samples….

10.2 Untested samples (blood and urine) shall be retained in a frozen condition for _____ (months/years). The regulatory agency must authorize the disposal of untested samples at the end of the designated retention period.

Comment: *The internal-use, Laboratory-assigned identification number is a key integrity measure to ensure that specific samples cannot be attributed to specific horses or individuals during the analytic process. This system effectively blinds the sample and thus unauthorized contact of laboratory personnel by external individuals cannot result in sample manipulation or the disclosure of analytic results pending the issuance of a final report.*

It is important that any irregularities associated with a sample (i.e. hemolysis, unusual odor, other evidence of sample degradation, absence of , or damage to, security tape, or errors in associated documents) be identified and addressed prior to the initiation of any testing. For example, the absence of a security seal may compromise defense of chain of custody and render a finding non-prosecutable. In consideration of that, the regulatory agency may elect to exclude that sample from analysis. If the analysis of a sample were to proceed without the laboratory consulting its client, the client may find itself in the untenable position of a non-actionable positive test.

The duration of sample retention will impact the cost to the regulatory authority. Positive samples (and split samples) should always be retained pending final case resolution. The retention period for negative samples should be determined in consideration of potential uses of those samples for research or intelligence gathering purposes. Regulatory agencies having budgetary constraints may find benefit in shorter retention periods for Negative samples.

The requirement that the laboratory secure permission from the regulatory agency for sample disposal allows for the selective long-term retention of specific samples of interest (i.e. those associated with a trainer having an exceptionally high winning percentage) such that they could be subjected to newly developed tests at a later date for the purpose of intelligence gathering. In order to reduce the cost associated with sample retention, the regulatory agency may elect to authorize the automatic disposal of TCO_2 samples immediately following analysis and the determination of regulatory compliance in the samples.

XI. Scope of Testing—Standard Post-Race Screening Analysis

11.1a. <u>All post-race samples</u> shall be subjected to instrumental screening analysis as described in section 11.3.

A limited number of ELISA tests, for substances lacking a validated instrumental screening method, may also be proposed.

The laboratory shall provide justification for each ELISA test it intends to apply to the regulatory agency's samples.

The laboratory must demonstrate that the sensitivity of proposed ELISA test kits is relevant to the agency's regulation of the listed substances.

ELISA tests may not be rotated without the prior written consent of the regulatory authority; all proposed tests must be applied to all post-race samples.

The use of thin-layer chromatography is not permitted.
Samples may not be pooled.
All samples shall be subjected to the same scope of analysis with respect to threshold substances.

OR

11.1b. All post-race samples identified for testing shall be subjected to instrumental screening analysis as described below. The process for identifying samples to be subjected to analysis is described in section 11.2.

A limited number of ELISA tests, for substances lacking a validated instrumental screening method, may also be proposed.

The laboratory shall provide justification for each ELISA test it intends to apply to the regulatory agency's samples.

The laboratory must demonstrate that the sensitivity of proposed ELISA test kits is relevant to the agency's regulation of the listed substances.

ELISA tests may not be rotated without the prior written consent of the regulatory authority; all proposed tests must be applied to all post-race samples.

The use of thin-layer chromatography is not permitted.
Samples may not be pooled.
All samples tested shall be subjected to the same scope of analysis with respect to threshold substances.

Comment:

Regulatory authorities are cautioned that on a per-substance basis, when large-scale screening is being done on multiple samples, Enzyme Linked Immunoassay (ELISA) testing can represent a significantly higher cost when compared to instrumental screening. Instrumental screening offers economy of scale that cannot be achieved by ELISA testing.

However, there may be justification for the intermittent application of specific ELISA tests or bespoke instrumental methods to perform population surveillance in determining if broad application of the additional tests is warranted. The contract should afford the regulatory authority sufficient latitude to permit timely responses to emerging or emergent substances.

With respect to the number of samples to be tested, per the 1991 McKinsey Report, "Building A World-Class Drug Detection System for the Racing Industry: A National Strategic Plan, (Appendix A)" there is merit in collecting more samples than are to be subjected to testing. Individuals associated with a sampled horse do not know whether the sample will be tested, and this knowledge, or lack thereof, serves as a low-cost deterrent. The testing of a subset of samples collected can represent substantial cost savings without reducing regulatory efficacy.

***Pooling of samples subverts medication regulation and should be expressly prohibited**. Pooling is the practice of combining samples and performing a single analysis on the composite sample. However, this practice substantially compromises the laboratory's ability to detect regulated or prohibited substances. For example, if four samples are mixed, one of which contains a prohibited substance and the other three do not, the prohibited substance's concentration has been reduced by 75%. At that lowered concentration, the substance may not be detectable, or if detected, determined to be an irrelevant finding. For substances having specified regulatory thresholds, this dilution effect means that an excessive concentration in a single sample is likely to go undetected.*

It is far better to test fewer samples well, than a multitude of samples poorly.

If 11.1a is selected, go to section 11.3

If 11.1b is selected select either 11.2a or 11.2b

11.2a A subset of each day's samples will be identified by the regulatory agency, or its designee, as candidate samples, eligible to be testing. All other non-'candidate' samples will be tested. Of the candidate samples, the laboratory shall randomly select xx% for testing, and retain the remaining yy% according to the provisions of Section X of this RFP.

OR

11.2b The regulatory agency, or its designee, will designate samples to be tested, and those to be retained, no later than the time of sample submission to the laboratory.

Comment: *If a regulatory agency elects to employ the McKinsey-recommended sampling/testing approach, it is preferable that the determination of those samples to be tested, and those retained, be done under 'blinded' conditions at the laboratory rather than by on-track personnel. This eliminates any perception (or opportunity) for individuals to be afforded preferential treatment or subjected to harassment through the testing process.*

Stewards, or individuals assigned with making sample designations (mandatory testing, or candidate sample—eligible to either be tested or retained) should be provided guidance as described in the McKinsey report.

The regulatory agency must also determine: 1) How long the retained samples must be kept by the laboratory; 2) If they can subsequently be analyzed for regulatory purposes; and/or 3) If they can be used for other, non-regulatory purposes (research, intelligence gathering, etc.

The retention of samples represents an added cost. The longer the retention period, the greater the associated cost. Samples retained long-term (> 6 months) should be maintained at or below -80^{o} C. Even at this lower temperature, some substances demonstrate instability, or their stability over time is simply unknown. Retention of samples beyond 6 months may be of questionable value when subjected to a cost-benefit analysis. If the regulatory agency elects to retain samples long-term, the laboratory should be required to provide affirmation that it possesses suitable storage facilities.

11.3 The post-race testing menu for all tested samples shall include instrumental screening analysis with a scope of testing encompassing all Controlled Therapeutic Medications (as published in the Racing Commissioners International [RCI] Model Rules Chapter 11) with testing sensitivities at or below regulatory thresholds, and the Thoroughbred Owners and Breeders' Association (TOBA) American Graded Stakes Committee (AGS) requirements.

Comment: *Current combined ARCI requirements should be applied to all samples. There is no credible justification for applying lesser testing standards, and thus more permissive medication policy, to non-Graded Stakes races. Competition, particularly when wagering is involved, cannot legitimately be conducted under varying 'degrees' of integrity.*

The TOBA AGS requirements have been transferred to the RMTC to curate and are currently under review. They will be updated to establish performance specifications relevant to current testing capabilities and industry needs. , The document will undergo annual review. Therefore, a regulatory agency's testing specifications may require amendment during a contract period to meet industry standards. This will require flexibility from the regulatory authority with respect to pricing in order to continue testing with the desired scope of analysis.

XII. Scope of Testing—Out-of-Competition Testing

12. Samples will be tested to a scope of analysis as described in (*insert agency's out of competition regulation*).

Samples may not be pooled.

The laboratory shall describe the validated methodology it employs for screening and for confirmatory analyses.

AND (Optional)

12a. Hair samples to be tested to a scope of analysis to include: *(anabolic steroids, clenbuterol, albuterol or as prescribed by the regulatory authority)*

The laboratory shall affirm it employs validated methodology that is included in its scope of IS)17025 accreditation.

In its response to this RFP the laboratory shall provide a redacted Report of Finding for a substance detected by hair analysis.

Comment: *Many existing out of competition regulations reference substances for which current testing methods do not exist. While this may result in limited enforcement opportunities, it is not unreasonable to identify these substances as banned. However, it is important that the regulatory agency understand any limitations with respect to testing for those substances. While the regulatory authority may not wish to perform public notification with respect to banned substances for which validated testing methods are unavailable, it is important that the agency has a clear understanding of the laboratory's analytic capabilities and limitations as they relate to enforcement of the agency's regulations.*

For jurisdictions having out of competition samples collected at sites other than locations with ongoing live race meets, it is necessary to define which party (laboratory or regulatory agency) is responsible for costs associated with sample shipment. This expense is likely to be variable and as such cannot be reliably projected. The cost associated with overnight shipment of a single out of competition test sample can exceed the price of sample analysis. Cost associated with shipment of sample sets other than those originating from tracks with ongoing race meets should represent an independent expense.

There can be interlaboratory variability with respect to hair processing (e.g. segmental or whole hair analysis, and any differences in managing pulled or cut hair). It is important for the regulatory authority to know how hair testing is done by its laboratory so that labs with comparable procedures can be solicited when split sample analysis is required.

XIII. Scope of Testing—TCO_2 (Total Carbon Dioxide) Testing

12. Blood samples identified for TCO_2 testing shall be subjected to analysis on a Beckman EL-ISE instrument or Gas Chromatography headspace using validated methodology. If the laboratory proposes to employ a different instrument, it must demonstrate the proposed instrument is equivalent to, and provides results consistent with analytical methods currently in use .

Samples shall be subjected to analysis within 120 hours of collection from the horse. The laboratory shall not analyze samples >120 hours post-collection.

The laboratory shall promptly notify the regulatory agency of any samples excluded from analysis due to sample age.

Comment: *The regulatory threshold of 37.0 mmol/l was developed through research studies in which the Beckman EL-ISE instrument was utilized. Analysis performed with other instruments may result in the reporting of substantially different concentrations of TCO_2 Rather than require regulators to adapt their TCO_2 threshold to the instrument, it is the obligation of the laboratory to demonstrate that the instrument it employs for TCO_2 testing performs consistently with the instrument that was used to establish the regulatory threshold.*

XIV. Scope of Testing—Samples derived from horses working for release from the Vets' List

14.1.a. Samples (blood +/- urine) shall be subject to complete screening consistent with analyses performed on post-race samples as described in Section 11. Samples may not be pooled.

OR

14.1.b. Samples (blood +/- urine) shall be subjected to targeted screening analysis (consistent with analytic methods applied to post-race samples as described in Section lI) for:_____(e.g. NSAIDs, corticosteroids, local anesthetics, anabolic steroids, bronchodilators). Samples may not be pooled.

AND

14.2.a All suspicious findings shall be subjected to confirmatory analysis consistent with the requirements of Section 11.

OR

14.2.b Suspicious findings shall be reported to the regulatory agency's key contact who will authorize confirmatory analysis on an *ad hoc* basis.

Comment: *Horses working for release from the Veterinarians' List should be subjected to testing to verify that the actual condition of the horse was not obscured by the use of medication. In most cases, blood is the only sample matrix available. Some*

jurisdictions may divert horses to a staffed Test Barn for sample collection, in which case paired samples can be acquired. The RFP should specify the sample matrix to be submitted for post-work testing: blood only, or blood and urine.

It is desirable that turn-around-time on these tests be as rapid as is reasonably possible without compromising the quality of testing.

In consideration of its regulations, the agency must decide if screening results (and the estimated concentrations generated) are sufficient for understanding the medication load carried by a horse during the observed workout. If so, confirmatory analysis may not be necessary, and turn-around-time can remain consistent with that for screening of post-race samples. If the results of post-work drug testing may be used to determine that a medication violation has occurred, confirmatory analysis (as required in Section 11) must be performed. The regulatory agency should be aware that this will increase cost and turn-around-time.

Regulators are cautioned that screening results, particularly for substances not included in the ARCI Schedule of Controlled Therapeutic Substances, are not definitive identifications. A screening result suspicious for an unusual, or previously unreported substance warrants a discussion with the laboratory and Equine Medical Director before any investigative action is taken or notification is made.

Note: *After the successful respondent laboratory has been identified, it is advisable that horsemen are informed of the projected turn-around time for this type of sample to assist them in planning of works and selecting races in which to enter their horses. The laboratory cannot be expected to expedite a sample or samples in order to accommodate a trainer's schedule.*

XV. Elective Testing—Targeted analysis for administered substances

15. At the discretion of the regulatory agency, samples may be submitted for targeted analysis for the determination of one or more specific substance(s).

The matrix (blood and/or urine) submitted shall be relevant to the agency's regulations with respect to the substance's threshold in blood and/or urine.

All samples submitted for targeted analysis will be submitted through the regulatory agency. The laboratory shall not accept privately or independently submitted samples for analysis without the prior consent of the regulatory agency.

For substances associated with a regulatory threshold other than the laboratory's limit of detection, quantitative analysis shall be performed. For

substances associated with a regulatory threshold at the limit of detection, qualitative analysis shall be performed.

The cost for targeted analysis can be substance-specific and may appropriately be addressed on a per-sample basis. Therefore, the laboratory shall establish pricing after receiving notification of the designated substance and inform the regulatory agency in advance of sample submission. The cost for targeted analysis shall not exceed the laboratory's pricing for analysis of a post-race sample of the same matrix absent laboratory justification for the increased cost and regulatory agency approval.

The laboratory shall provide its report to the regulatory agency. Any communications regarding any and all aspects of the analysis shall be between the regulatory agency and the laboratory. The laboratory shall not consult directly with the submitting veterinarian, trainer, or owner without the prior consent of the regulatory agency.
The laboratory shall not accept samples for analysis related to doping control (regulated therapeutic medications or banned substances) from any individual or agency, other than those with which it has contractual agreements, without the prior consent of the (*insert name of regulatory agency*).

Comment: *The ability to offer clearance testing for regulated substances provides stakeholders assistance in their compliance with regulations. However, there is risk that this service could be used to titrate doses or alter administration times in order to subvert regulations. (The regulatory agency should require specific information pertaining to dose and route of administration when accepting these samples for analysis.)*

While it is reasonable for laboratories to accept external samples for analysis unrelated to doping control (i.e. pre- or post-purchase testing), it is important to constrain the lab's ability to accept of external samples where analytic results could be utilized to subvert the regulatory agency's regulations.

XVI. Scope of Testing—Substances/unknowns

16. For substances bearing content labels, the laboratory shall perform analysis consistent with the RMTC Protocol for Verification of Label Ingredients. (Appendix B)

For substances lacking a list of label ingredients, the laboratory shall perform analysis consistent with the RMTC Unknown Sample Protocol. (Appendix C)

XVII. Subcontracting or outsourcing of work

17. The laboratory may not outsource, or engage subcontractors for, any work related to the regulatory agency's samples for any reason without the prior written consent of the regulatory agency.

Any such request must be fully justified and include documentation of the qualifications of the contractor, affirmation that the analytic requirements of the regulatory agency will be met, and that chain of custody procedures will remain intact. The proposed contract laboratory shall affirm its willingness to accept the agency's samples. The duration of service to be provided by the contractor shall be defined.

The use of a contractor by the official laboratory shall not justify any increase in cost to the regulatory agency UNLESS the work to be performed by the contractor represents an agency-initiated change in its required scope of testing.

Comment: *There may be a number of reasons for the use of a contract laboratory, some good, some not. What is important is that if a contract laboratory is to be used, that there is no vulnerability to the regulatory agency in terms of the quality of testing and the defensibility of any actionable finding that might result from outsourced work. In some cases, the need for a contract laboratory is known at the time the RFP response is submitted. Quantitative analysis for cobalt and other metals is performed on instruments rarely possessed by drug testing laboratories. It is anticipated that for the foreseeable future, in most cases analysis for cobalt and other metals will be outsourced. Laboratories lacking the ability to perform confirmatory analysis for erythropoietin or darbepoetin will have established relationships with laboratories having a validated confirmatory method. In these circumstances, the contract laboratory shall be identified in the RFP response.*

In the event that the need to outsource analyses was not predetermined, it is important that the selected laboratory affirm its willingness to accept the samples and perform its work to the agency's specifications and desired turn-around-time.

XVIII. Changes to Scope of Testing

18. The laboratory may not amend the scope of testing for any sample(s), without securing prior permission from the regulatory agency.

The regulatory agency may request changes to the scope of testing during the period of the service contract. Costs associated with method validation for implementation of thresholds established by the ARCI and adopted by the regulatory agency shall be absorbed by the laboratory.

Costs associated with method validation for thresholds other than those established by the ARCI shall be borne by the regulatory authority establishing the threshold.

For other requests by the regulatory agency for changes to the scope of testing, the regulatory agency and laboratory shall identify costs associated with the projected work. Prior to the commencement of method development and validation, the regulatory agency and laboratory shall, to the satisfaction of both parties, determine how the method development, validation and subsequent testing will be funded and that adequate funding exists.

Comment: *It is important that the regulatory agency understand what testing is, and is not, being performed. This should be clearly established through the RFP process. A change in the scope of testing—whether it applies to all samples or a single sample—must never be implemented without the knowledge and consent of the regulatory agency.*

This requirement also serves as a quality control measure to ensure that the blood and/or urine collection process obtains specimens in volumes that do not constrain the laboratory's work, and that samples are being consistently subjected to the scope of analysis as prescribed by the regulatory agency.

XIX. Turn-around-times—Screening and Confirmatory Analyses

19. The laboratory shall electronically issue screening reports (inclusive of post-race, pre-race TCO_2, post-work, and out of competition tests) within _____(business/calendar days) of its receipt of samples to a distribution list provided by the regulatory authority. In the event the laboratory determines that a screening report cannot be reported as scheduled, the laboratory shall promptly notify the regulatory authority, provide a justification for the delay and request the regulatory agency for an extension. Extensions shall be for a defined period as warranted by the event that resulted in the delay.

Confirmatory analysis, when warranted, shall be completed within _____(business/calendar) days of the issuance of the screening report. In the event the laboratory determines that a final report cannot be reported as scheduled, the laboratory shall promptly notify the regulatory authority, provide a justification for the delay and request the regulatory agency for an

extension. Extensions shall be for a defined period as warranted by the event that resulted in the delay.

Comment: *Generally, screening reports should be produced to the regulatory agency within 4-7 days of the lab's receipt of samples. Confirmatory analyses for controlled therapeutic substances should be reported within an additional 5-7 business days. Other substances may require additional time based on the availability of reference standards and/or validated testing methods. In these cases, turn-around-time will, out of necessity, be longer. In these instances, the laboratory should promptly communicate to the regulatory agency an anticipated timeline for completion of the required work.*

For analysis of confiscated materials, targeted analysis for medication clearance, and analysis of sample other than those described, turn-around-time may be difficult to define in advance of the work's actually having been performed. It is likely that these matters will need to be addressed at the time of sample submission and in consideration of the circumstances surrounding the need for the analysis.

Note: *A contractual requirement for more rapid turn-around-times is associated with increased cost. For jurisdictions under budgetary constraints, flexibility with respect to turn-around-time requirements may represent an opportunity to conserve limited funding.*

XX. Quality Control/Quality Assurance

20. The laboratory shall have, and identify to the regulatory authority, a designated quality control officer who is responsible for implementation of an internal proficiency-testing program comprised of analysis of single blind samples and routine performance reviews of all individuals having contact with the regulatory authority's official samples.

Internal blind samples shall contain substances of current interest at relevant concentrations. The internal proficiency-testing program shall have, as a minimum, a scope of coverage that encompasses routine screening tests.

Results of internal proficiency testing shall be provided to the regulatory authority on a (quarterly/semi-annual/annual) basis. The regulatory agency should be promptly notified by the laboratory key contact when analysis of an internal blind sample fails to detect the analyte present. The laboratory's corrective action process should be documented and provided to the client upon request.

The laboratory shall participate in external quality assurance programs (EQAP), as required through RMTC and ISO 17025 accreditation. In its

response to the RFP, the laboratory shall inform the regulatory authority of the programs in which it participates, the number of EQAP samples it receives in a 12-month period and provide justification for the EQAPs in which it is enrolled. The laboratory key contact shall provide the regulatory authority the EQAP-issued report of the laboratory's performance within 7 working days of receipt of the results of the tests. The laboratory shall provide its client(s), within 30 days, a written plan to remedy any deficiencies identified through the EQAP process.

OPTIONAL

20a. The laboratory shall participate in a passed-sample exchange program with one or more RMTC (or the international equivalent) accredited laboratories. (number) sets of (blood and/or urine) should be exchanged on a (quarterly/semi-annual/annual) basis. Results shall be provided to the regulatory authority in a timely manner.

Comment: *Quality assurance programs are critical to assessing laboratory capabilities. External Quality Assurance Program (EQAP) providers select substances that are relevant to the needs of racing regulators. While the client may not be familiar with the substance, or its effect, the client does need to know if the laboratory is capable of its detection. The client must be notified in a timely manner of the results of EQAP participation. Even the best EQAP currently available uses a single blind system—in which the EQAP samples are clearly indicated as such. This then results in a test of the laboratory's capabilities, but does not clarify that these capabilities are fully applied to the regulatory authority's samples.*

The passed sample exchange is a useful adjunct to the EQAP in that the samples are derived from actual race horses, and the sub-threshold medication load is more reflective of that which is routinely seen by the laboratory. Assuming consistency in methodology and sensitivity, there should be good agreement between the two laboratories. Recognizing that these samples will also be identified to the laboratory, it is possible that they, like the EQAP samples, could be subjected to a higher level of scrutiny than that applied to the lab's routine work. Were this to be the case, substances identified by the second lab, but not by the primary lab, may be identified for addition to the scope of analysis or refinement in the laboratory's sensitivity. Pricing for a passed-sample exchange program can be established on a per-sample basis independent of the costs associated with the analysis of official samples, or it can be pro-rated and added to the per post-race sample cost. Either way, this program will result in some increase in cost to the regulatory authority. However, it is money well spent. If there is concern about disclosure of results vis-a-vis samples originating from another laboratory, it may be prudent to execute an MOU establishing confidentiality and defining the use of the information generated.

Note: *Passed sample exchange programs can be impacted by differences in medication regulations between jurisdictions. For the results of a sample exchange to be meaningful, it is important for the regulatory agency to determine if a sample reported as passed in one jurisdiction, but failed in another, is indicative of analytic differences OR differences in the respective agencies' regulation of that substance.*

XXI. Reports / Communications/Support to Regulatory Agency

21. Screening reports, final reports, reports of adverse findings, and data (litigation) packets shall meet all ISO 17025-2005 and RMTC criteria.

Reports shall be distributed electronically to a distribution list provided by the regulatory authority or via facsimile to a location designated by the commission. Hard copy reports bearing original signatures will be produced upon request and delivered by First Class US mail unless otherwise requested. Costs associated with expedited or alternative delivery methods will be assumed by the regulatory authority.

Data (litigation) packets shall be delivered to the regulatory authority electronically or via express mail no later than 7 business days after the regulatory agency submits its request for the laboratory to compile the packet.

Only upon prior authorization by the regulatory agency may the laboratory discuss or disclose any methods, testing sensitivities, limits of detection or other information relevant to the testing of the agency's samples.

Should data derived from the regulatory authority's samples be intended for use in a scientific publication, the laboratory shall solicit permission from the regulatory authority and execute an appropriate non-disclosure agreement prior to submission of a manuscript to a journal for review.

The laboratory director shall serve as expert witness on behalf of the regulatory agency, and provide consultation, oral testimony, and scientific references as warranted, in the adjudication of cases arising from a laboratory report of finding.

AND

21.a Costs associated with travel and time for up to _____ appearances, by the laboratory director or other laboratory personnel in testimony and testimony preparation, will be borne by the laboratory.

OR

21.b Costs associated with travel and time, consumed by the laboratory director or other laboratory personnel in testimony and testimony preparation, will be reimbursed by the regulatory agency at rates current at the time of travel as established by state government.

Comment:
Screening reports should include the following information: Date of report issuance, origin of samples (racetrack), collection date, date received, date analysis was initiated, condition of samples, shipping seal number, agency sample ID number, laboratory internal sample reference number, sample type, analytic result, total number of samples and analytic methods performed. If all samples are passed as a result of screening analysis performed, the report should indicate "No violations detected" or comparable verbiage. For samples identified for further analysis, there should be an indication of "Pending" or comparable verbiage.

Reports of failed samples should also include the exact finding. For substances having regulatory thresholds above the laboratory's limit of detect, the report should contain the concentration determined, and the laboratory's measurement uncertainty. (For a substance to be reported by the laboratory as detected in a concentration in excess of the regulatory threshold, the detected concentration must exceed the threshold plus the method's uncertainty measurement.) The method used for confirmatory analysis should be identified. Opinions, to the extent that they are required, must be clearly identified as such. Qualitative analysis is performed for substances associated with screening limits or substances regulated by laboratory limit of detection. When qualitative analysis results in the issuance of a Report of Finding the laboratory may inform the regulatory authority of its estimated concentration of the substance for the purpose of split sample laboratory solicitation.

Case preparation and testimony by key laboratory personnel (most often the Laboratory Director) can be important to an agency's prosecution of regulation violations. Recognize that in-person appearances at hearings represent substantial expense, as well as time away from the laboratory and the performance of other duties. Skype or videoconferencing may represent cost-effective, and legally acceptable, alternatives for depositions and testimony.

Confidentiality is important AND official drug testing results can generate useful, and relevant research. The balance to be achieved is that if data derived from an agency's samples are to be a component of research, the laboratory shall be required to redact or refrain from publishing any information that identifies the regulatory authority, the racetrack, date, or specific race.

XXII. Historical information

22. The laboratory shall provide a history of its experience in analytic work relevant to the scope of work required by the regulatory agency. The laboratory shall provide contact information for three clients having similar service requirements to those of the issuing agency.

For laboratories performing equine drug testing services for less than five years, the laboratory shall, in its response to the RFP, agree to provide a performance bond for the period of the contract.

The laboratory shall provide information related to the dismissal of any analytic findings related to failure in chain-of-custody, erroneous or inadequately documented analytic methods, data analysis error, or other event attributable to the laboratory.

The laboratory shall provide information, to the extent it has been notified by its clients, related to the dismissal of any analytic findings related to a reference laboratory's split sample analysis failing to support the primary laboratory's finding.

The laboratory shall provide information related to the determination by any hearing officer or quasi-judicial official that testimony provided by laboratory personnel was not credible.

The laboratory shall disclose if a contract with a regulatory agency has ever been terminated during the period of the contract, and if so, the laboratory shall describe the circumstances resulting in the early termination of service.

Comment: *The client needs to know that the laboratory's work will withstand the degree of scrutiny that may be expected in a legal challenge. Previous failings, while not necessarily justifying a laboratory's exclusion from the selection process, should be noted and adequately researched.*

XXIII. Research

23. The laboratory shall provide a summary of its ongoing and completed research relevant to equine drug testing, the regulation of therapeutic medications, or the detection of banned substances in racehorse samples.

The laboratory shall document the activities of senior staff relevant to meetings and outreach with industry representatives, stakeholders, and licensees.

The laboratory shall describe its ongoing efforts to monitor analytical trends, gather intelligence, and identify substances representing emerging threats to the integrity of the sport and the safety of its participants.

Comment: *Research is a requirement for RMTC accreditation. It is worth knowing if completed research is relevant to the needs of the regulatory agency, or the racing industry at large. Further, it will be helpful to know if the laboratory is willing/able to investigate questions identified by its clients.*

If the regulatory agency has the inclination and ability to fund research, the RFP could also include language describing the process for the determination of pricing, work timelines and research work product. Alternatively, this could be a separate agreement, independent of the drug testing contract.

For regulatory agencies also having jurisdiction over Greyhound racing or other animal sport, the above language may be expanded to reflect the additional research interests.

XXIV. Value-added services

24. The laboratory shall describe any value-added services it intends to provide beyond those required in this RFP.

Comment: *The availability of the laboratory director for regularly scheduled conferences (in person or via telephone or video conferencing) to discuss aspects of the regulatory agency's testing program, attendance at agency-hosted meetings with stakeholders, or providing additional intelligence derived from the agency's samples represent examples of value-added service that may be of substantial benefit to the client. It is worth asking the laboratory what sets it apart from other RMTC accredited laboratories.*

XXV. Disclosure of competing business interests or conflict of interest in key laboratory personnel

25. The RFP response shall include disclosure of any competing business interests or conflicts-of-interest in any laboratory personnel having purchasing authority or the ability to determine analytic practices.

Comment: *The regulatory agency must have confidence that decisions made within the laboratory are in the best interests of the analytic needs of their clients. If a chemist is also associated with a company that manufactures test kits that are utilized in the analysis of a client's samples, there is an obligation to acknowledge and defend such use.*

XXVI. Default on contractual obligations

26. The laboratory's failure to perform in accordance with all terms of the contract shall provide the state racing authority certain rights. In such an event, the racing authority may require:

1) A meeting between representatives of the racing authority and laboratory management;

2) A corrective action plan by the laboratory to bring the laboratory into compliance with the terms of the contract. The plan must include:

- **A. Identification of areas in which the laboratory is in breach of the contract;**
- **B. Clarification as to the cause(s) of deficiencies and a detailed plan to prevent said deficiencies in the future;**
- **C. A list of specific actions and deadlines for fulfillment of those obligations in arrears; and,**
- **D. A bond payable to the state racing authority in an amount agreed between the parties.**

The racing authority is not required to allow any corrective action and shall reserve the right to terminate the contract in accordance with its terms.

Comment: *Most contracts contain provisions for termination of the agreement should either party default on its obligations. However, simply terminating a relationship with a laboratory may not be a practical option for the client whose regulatory duties cannot be suspended pending the identification of an alternate laboratory. This section establishes an incentive for the remediation of deficiencies, and an alternative to unscheduled termination of the relationship.*

XXVII. Pricing

Historically the cost of confirmatory analysis of samples has been included in the per sample pricing offered by the laboratory. If the real cost of a confirmatory analysis is $1000 and the suspicious rate is 2%, then the cost per paired blood and urine is increased by $20 to cover the cost of the testing (2 x $1000/100 paired samples = $20 per paired sample). This pro-rated inclusion of confirmatory analysis costs is helpful to regulatory agencies for budget planning purposes but is only beneficial to clients and laboratories when the occurrence of suspicious samples is accurately projected. If the actual occurrence of suspicious samples falls below the projected rate, the client is paying for unused testing services. If the number of suspicious findings increases when compared to the projected rate (e.g., when new thresholds are adopted, or substances are added to the scope of analysis), the laboratory's expenses associated with testing can be much greater. If the projected rate of suspicious samples is 2%, but the actual suspicious rate is 7%-12%, then the cost per paired blood and urine would

need to be increased by $50-100 to cover the additional costs of analysis. Absent a fee adjustment, the laboratory performs testing at a loss, and the business model is unsustainable.

An unanticipated increase in workload may be expected to result in delays in turn-around-time unacceptable to the regulatory authority.

Further, the business model that does not designate specific payment for testing of suspicious samples establishes disincentives for a laboratory to expand its scope of testing or to pursue and confirm suspicious findings.

A preferable business model may be one in which each confirmatory analysis is billable at an established rate. This would incentivize laboratories to expand the scope of testing and to pursue findings, and also incentivize regulatory agencies and racetracks to reduce findings through educational programs and stakeholder outreach.

27. The laboratory shall offer per-sample pricing, inclusive of the provisions of Sections II-XXVI of this RFP, as follows:

AND

Paired-post race samples

27a1. A. Paired (blood and urine) post-race sample subjected to screening analysis as described in Section XI, and

B. Confirmatory analysis of post-race sample (on a per matrix basis) identified as suspicious through screening analysis, as required for issuance of a final report.

OR

27a2. Paired (blood and urine) post-race sample subjected to analysis as described in Section XI, and inclusive of all analyses required for the issuance of a final report.

AND

Blood-only post-race samples

27b1. A. Single matrix (blood only) post-race sample subjected to screening analysis as described in Section XI, and;

B. Confirmatory analysis of single matrix post-race sample, identified as suspicious through screening analysis, as required for issuance of a final report.

OR

27b2. Single matrix (blood only) post-race sample subjected to analysis as described in Section XI, inclusive of all analyses required for the issuance of a final report.

AND

Out-of-competition testing

27c1. A. Single matrix (blood only) out of competition sample subjected to screening analysis as described in Section XII, and;

B. Confirmatory analysis of single matrix out-of-competition sample identified as suspicious through screening analysis, as required for the issuance of a final report.

OR

27c2. Single matrix (blood only) out-of-competition sample subjected to analysis as described in Section XII, inclusive of all analyses required for the issuance of a final report.

AND (Optional)

27c3. Single matrix (hair) out-of-competition sample subjected to scope of analysis as agreed upon in contract.

Comment: *Currently most out of competition samples are blood only, single matrix. As out of competition sampling is usually performed absent advance notification, the collection of a urine sample can be problematic and is rarely attempted, let alone achieved. However, for jurisdictions contemplating expanded scopes of analyses for out of competition samples, it is advisable to solicit additional pricing, comparable to that described above in 26c1 or 26c2, for paired samples.*

Hair testing is becoming an increasingly utilized method for the control of anabolic steroids and beta2 agonists (e.g. clenbuterol and albuterol). It is important to remember that there are many substances that are not amenable to detection by hair testing. Regulatory authorities should consult with the laboratory to determine the lab's capabilities relevant to the regulator's needs.

AND

TCO_2 Testing

27d. Single matrix (blood only) pre- or post- race sample designated for TCO_2 analysis as described in Section XII, and inclusive of all analyses required for the issuance of a final report.

AND

Analysis of Samples Derived From Horses working for Release from the Veterinarians' List

27e1. A. Single matrix (blood only) post-exercise sample subjected to screening analysis as described in Section XIV, and;

B. Confirmatory analysis of single matrix post-exercise sample identified as suspicious through screening analysis, as required for the issuance of a final report.

Comment: *Jurisdictions for which the detection of a controlled therapeutic medication or a banned substance in a post-exercise (non-race) sample would not constitute a violation, may elect not to solicit B pricing as described above. The pricing described above would be applicable to those jurisdictions in which confirmatory analysis is performed at the discretion of the regulatory agency.*

OR

27e2. Single matrix (blood only) post-exercise sample subjected to analysis as described in Section XII, inclusive of all analyses required for the issuance of a final report.

Comment: *As these samples are derived from horses following scheduled, observed exercise, urine sample collection may be possible. For those jurisdictions intending to perform urine collection, pricing for paired (blood and urine) samples, comparable to that described in 26e1 and 26e2, should also be solicited.*

The Model Rules' prohibition on stacking of NSAIDs and Corticosteroids requires analysis of blood and urine. Blood testing alone will not provide adequate analytical support for the prohibition on stacking. The urine collection requirement may require

regulators to contemplate Test Barn operations at times in addition to standard post-race activities.

AND

Analysis of confiscated, or otherwise acquired, substances

27f. A. Analysis of substances with list of labeled ingredients as described in the RMTC Protocol for Verification of Label Ingredients, and;

B. Analysis of substances lacking a list of label ingredients, as described in the RMTC Unknown Sample Protocol.

AND

Miscellaneous

27g. Pricing of laboratory-sourced materials, intended for uses other than the analysis of official samples, as follows: *(Insert itemized list—i.e. blood collection tubes, needles, urine sample cups, etc.)*

XXVIII. Evaluation of Proposals Received in Response to RFP

Comment: *In addition to the RFP, the issuing agency may also consider requiring presentations from representatives of the responding laboratories and/or the analysis of blind samples provided by the issuing agency. An oral presentation by key laboratory personnel may be helpful in determining how the laboratory interacts with clients and industry stakeholders, and/or communicates information in hearings. The analysis of blind samples may be helpful in determining the laboratory's familiarity with the agency's regulations, and in evaluating proposed methods of communication between the laboratory and the regulatory authority.*
The RFP requests a large amount of information that the regulatory agency must evaluate relevant to its needs. It is helpful to use a consistent format when evaluating laboratories' responses in order to recognize and consider the impact of substantive differences.

Cost comparisons are useful only if the proposed work
1) meets the standards of the regulatory agency; and,
2) is consistent between laboratories' responses.

A description of the evaluation criteria and selection process should be distributed with the RFP.

The following evaluation form may be used as a template for objective assessment and comparison of laboratories' responses. The regulatory agency must determine which criteria should be assigned pass/fail status. Failure to achieve 'Pass' status on any of these criteria renders the proposal unresponsive and excluded from further consideration. Other criteria may be evaluated on a points system, similar to that described below.

RFP EVALUATION FORM

Pass/Fail Criteria:

1. Proposal received on or before submission deadline Yes No
2. Laboratory is RMTC accredited Yes No
3. Laboratory applies validated methodologies for the detection of all Controlled Therapeutic Substances at threshold concentrations (as exist in RCI Model Rules effective at the time of the issuance of the RFP) Yes No

Evaluation Factors:

1. Qualifications and capabilities of vendor (*25 points maximum*)
    a. Proposed staffing for the management and analysis of the agency's samples
    b. Chemists/analysts with advanced degree(s)/analytic experience
    c. Laboratory director degree/experience
    d. Staff available for consultation; availability outside of normal business hours
    e. Description of other clients
        i. Current
        ii. Previous
    f. Performance history—meeting contractual deadlines; outcome of split sample analyses; defense of findings in hearings, etc.
    g. Experience in equine testing
    h. Identification of person(s) with AORC membership
2. Deliverables and work plan (*30 points maximum*)
    a. Sample management
    b. Turn-around-times—screening and confirmatory analyses
    c. Communications with regulatory agency
    d. Testimony/Support to regulatory agency
    e. Value added services (not requested by RFP)

3. Total proposed cost (*25 points maximum*)
    a. Cost for blood/urine samples
    b. Cost for TCO2 samples
    c. Cost for out-of-competition samples
    d. Cost for "special" services

    Comment: *#3 should be customized to be consistent with pricing requested in Section XXVII of the RFP.*

4. Equipment and methods of testing (*10 points maximum*)
    a. Equipment designated for testing of the agency's samples
    b. Testing methodology
    c. Quality assurance/quality control program
    d. Development of new/advanced testing procedures
5. Industry leadership (*10 points maximum*)
    a. Published scientific articles
    b. Presentations
    c. Stakeholder interaction/communication
    d. Collaboration with other laboratories

    Comment: *If the regulatory agency elects to require blinded sample analysis, or oral presentations, points should be redistributed to include the additional evaluation criteria.*