AORC Guidelines

Standard Operating Protocol for Analytical Data Review (Phase II)

Prepared by the Analytical Data Review Board and first issued in December 2019

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1. POLICY

1.1 BACKGROUND

Accurate analytical data are fundamental to the reporting and investigation of samples containing prohibited substances. These are often challenged in subsequent inquires or proceedings.

The idea of a "Review Board" is not new. John Jackson said in 1985,

> *"And it's a disservice to the profession to have our experts in chemistry contest one another's abilities in cases where the original positive finding is absolutely valid. Establishing an analytical board of review would seem logical, to provide a neutral arbiter for deciding the validity of a positive test report...*
>
> *"Our state of affairs where chemist openly contests chemist is detrimental to the profession: We have a tearing down of integrity, a pulling apart rather than a pulling together...*
>
> *"What I've said reflects my concern for continued public respect and confidence in – and the integrity of – the profession."*
>
> "A Lawyer's View", in Proc. 6th ICRAV, 1985, Hong Kong

Similar discussions in early 2005 resulted in a proposal to form an AORC Analytical Data Review Board (ADRB) to review, on a voluntary basis and according to the relevant rules of the authorities, the analytical data provided by its members. This ADRB could help assure the quality of the end products of AORC members, even help them to improve and establish their professional credibility. It could also help to expose unethical and unprofessional criticisms, and help racing authorities by providing them with useful and relevant third-party expert opinions.

The idea was supported in principle by the AORC Executive Board in Oct 2006 at the 16th ICRAV in Tokyo. Membership of an ad hoc committee on data review was officially established and announced in Aug 2008. A brief proposal was presented by the Chair of the ad hoc committee at the AORC Business Session of the 17th ICRAV in Antalya in Oct 2008, which was well received by the attending members.

This proposal was developed further by the ad hoc committee, and an operational model was presented at the AORC Business Session and Roundtable of the 18th ICRAV in Queenstown in Mar 2010, and circulated as part of the AORC Bulletin 560 in Nov 2010.

In Jan 2011, the AORC Executive Board agreed with the establishment of the Analytical Data Review Board (ADRB), and that the ad hoc committee will become a standing committee (i.e., the full ADRB) responsible for convening and administering a 3-person Data Review Panel whenever requested by, in most cases, an AORC member (Professional or Fellow). As from 1 Jan 2020, the ADRB and all Data Review Panels will operate in accordance with the present Standard Operating Protocol (Phase II).

1.2 COMPOSITION & MANDATE OF AORC ANALYTICAL DATA REVIEW BOARD

Composition: Nine professional, fellow or emeritus members appointed by the AORC Executive Board on normally 3-year renewable terms. It would be preferable that each of the American, Asian and European regions is represented by three members. One of the nine members is designated as the Chair of this standing committee.

Initially, the terms of office of some members will expire either 12 or 24 months after official implementation of the ADRB so as to achieve staggered terms of office, with the terms of 3 members expiring every 12 months.

The ADRB Chair is either appointed by the AORC Executive Board or to be selected among the ADRB members.

To ensure independence, each ADRB member receives no honoraria for their voluntary service. However, the AORC Executive Board may decide to grant exceptional and discretionary honoraria to certain ADRB members should their workload become excessive.

All ADRB members will sign confidentiality undertaking. In addition, they will undertake not to be engaged by a Trainer or Person Responsible in (i) the cases they have reviewed, and (ii) any other regulatory cases during their terms on the ADRB and the 6 months thenafter.

Mandate: To administer all requests and convene a 3-person Data Review Panel to review submissions of analytical data together with reported or proposed findings and relevant information with the objectives of:

- enhancing the reliability and scientific acceptability of those findings;
- helping less experienced AORC members establish their confidence and professional credibility;
- enhancing the standing and reputation of racing chemists in general; and
- assisting regulatory authorities by providing independent and relevant third-party expert opinions.

1.3 COMPOSITION AND RESPONSIBILITY OF THE AORC DATA REVIEW PANELS

Composition: For each request from an AORC professional or fellow member, the ADRB administrator (normally the ADRB Chair) will appoint three ADRB members to form a Data Review Panel, one of whom to be designated as the Chair of the panel. When making these assignments, the ADRB administrator bears in mind any potential or perceived conflict of interest, workload, expertise and other considerations. On occasion, an AORC professional, fellow or emeritus member may be co-opted by the ADRB Chair into the ADRB and be appointed to a specific Data Review Panel. Co-opted individuals

are subject to the same confidentiality undertakings applicable to regular ADRB members, and they will undertake not to be engaged by the Trainer or Person Responsible in all the cases they have reviewed or agreed to review.

Responsibility: To independently review the supplied analytical data associated with the reported/proposed findings of a prohibited substance in a regulatory sample so as to enhance the reliability and acceptability of those findings. Analytical data from reported or pre-reported cases can be accepted for review in the current phase (Phase II).

2. PROGRAM ADMINISTRATION

2.1. REQUEST FOR REVIEW

a) This service is entirely optional. However, the relevant regulatory authority should have authorised the use of the ADRB, either specifically for the submitted data or generically as part of the working arrangement between the laboratory and the regulatory authority. A data review request form (Appendix 1) must be completed.

b) A request may be initiated by an AORC professional or fellow member (or by a regulatory authority). Such request is made confidentially to the ADRB administrator (normally the ADRB Chair) via confidential e-mail or courier. This request must be accompanied by the sample code, the identity of the reporting authority, the analytical data obtained, and the reported or proposed findings. Information normally sent to the regulatory authority should be included. In general, the same sample and analytical data may not be submitted more than once for review.

c) If courier dispatch is used, electronic files should be included for ease of further distribution. For requests initiated by an AORC professional or fellow member, the analytical data should have been generated by the initiator or one under his/her direct supervision.

d) The initiator should also specify the route for receiving the confidential report and provide the necessary contact information to facilitate such reporting.

e) The submission should be accompanied by a check-list of applicable criteria (such as AORC MS Criteria, ILAC-G7, IFHA's ISL/IRL, local criteria, etc.), and/or any applicable rules (such as the definition of prohibited substances). Inadequate data provided can lead to a "non-endorsed" opinion.

f) Where practical, extraneous information should be excluded or obliterated. All analytical data and confidential information submitted will be destroyed within one month from completion of all relevant inquiries/proceedings or four months after completion of the requested review whichever is later, or at any time requested by the initiating person or authority.

g) The initiator may exclude, without stating the reason, up to 3 of the 9 ADRB members from being appointed to the Data Review Panel. However, any request to appoint certain ADRB member(s) on the Data Review Panel cannot be entertained.

h) The ADRB administrator (normally the ADRB Chair) has the right to reject or terminate a request for review if the necessary data or information cannot be provided within 2 weeks of initiating a request. The ADRB Chair will refer cases of suspected abuse of this service (including provision of falsified data or information) in the first instance to the AORC Executive Board, who will inquire on the matter and may decide to inform the relevant authority.

i) The ADRB administrator makes reference to the sample code, reporting authority and the reported or proposed substances (findings) to assign a 3-person Data Review Panel. In general, ADRB members will not be asked to review cases arising from their own authorities. Those agreeing to serve on this Data Review Panel are expected to abide by the review deadline.

As soon as the composition of the Data Review Panel is confirmed, the ADRB administrator will forward the full set of data and information to all panel members.

j) During his/her extended period of absence from office, the ADRB Chair may delegate the role of ADRB administrator temporarily to another member of the ADRB.

2.2 REVIEW CONDUCTED BY THE DATA REVIEW PANEL

a) Each member of the Data Review Panel will independently review the supplied data and information, and provide only an "endorsed" or "not endorsed" view to the Chair of Data Review Panel via confidential e-mail within the agreed deadline. Discussions within the panel for clarification purpose are allowed; however, each panel member should form his/her own opinion independent of the views of the other members.

b) Such reviews should not include any interpretation of the relevant rules, and should only involve the application of the relevant rules.

c) The 3-person Data Review Panel operates on a majority opinion. On behalf of the panel, the Chair then issues a confidential report (on official AORC letterhead) by e- mail solely to the initiator (or whichever recipient designated by the initiator). This report will include only (i) the sample code, reporting authority and reported/proposed findings, (ii) the date of receipt of all relevant data and information, (iii) either an "endorsed" or "not endorsed" view, and (iv) whether the panel's view has been based on a majority or unanimous opinion. The composition of the Data Review Panel is revealed in this report. An example of a review report is shown in Appendix 2.

d) The target turnaround time is set at "within 5 working days (one week) from receipt of all relevant information" for issuing a written report by the Chair of the Data Review Panel.

e) The opinion of this Data Review Panel is final. However, if the initiator disagrees with such opinion, an appeal may be made to the AORC Executive Board (subject to payment of an appeal deposit of USD 200 to the AORC) to have the identical submission reviewed one last time by another Data Review Panel. If the AORC Executive Board sustains the appeal, the appeal deposit will be refunded, and this will be the only exception when the same sample and analytical data may be submitted to the ADRB more than once for review.

2.3 FEES FOR DATA REVIEW

a) Nominal administrative fees are to be levied against the initiating AORC professional or fellow member as follows:

- Each member may have one sample reviewed for free per year (starting from the date the analytical data were received for the first time);
- USD 100 per sample for the next 3 samples within the year; and
- USD 300 per sample for all subsequent samples within the same year.

b) Such fees are payable to the AORC and will be billed in arrears by the AORC Executive Director in generic terms for consultancy on a particular date.

c) Requests for review can also be made by a regulatory authority (or by an AORC affiliate member via the relevant regulatory authority). In this case, the normal professional fees of US$600 per positive sample will be charged by the AORC.

d) The A and B portions of the same sample are considered separate samples. Different biological matrices (such as urine and blood samples) collected at the same time from the same subject, even with the same sample code, are considered separate samples unless the confirmation data have been acquired from only one matrix. Requests can also be made to review the data originating from either one or all of the matrices analysed.

2.4 COST RECOVERY (EXCLUDING PERSONNEL COSTS)

The AORC Executive Director will reimburse the direct costs (such as courier charges and other administrative expenses) incurred by members of the ADRB.

2.5 FURTHER PROFESSIONAL ASSISTANCE

Neither the AORC nor its ADRB will have any further obligation on the cases reviewed.

Should further comments or professional assistance be required, beyond the "endorsed" or "not endorsed" opinion of the ADRB, this becomes a private arrangement between the relevant ADRB members (normally but not necessarily just the Data Review Panel chair) and the initiating member/authority.

2.6 PROGRAM REVIEW

It is the responsibility of the ADRB Chair to oversee the service provided by the ADRB and, together with other members of the ADRB, propose improvements of the program.

Appendix 1: Data Review Request Form

CONFIDENTIAL

Dear AORC ADRB Chair (contact details as posted on the AORC website),

1. I, _____[name]_____ of _____[laboratory/authority]_____ wish to submit the attached analytical data for review by the ADRB. Details of the reported/proposed findings are:

    a. Sample code:

    b. Reporting authority:

    c. Findings reported/to be reported:

    d. Applicable criteria and rules (check all that apply):

    ☐ AORC MS Criteria ☐ ILAC-G7 ☐ ISO/IEC 17025 ☐ IFHA IABRW Art. 6

    ☐ IFHA ISL/IRL ☐ RMTC LabAccr.Reqt.&Oper.Stds ☐ ARCI Rules&Stds

    ☐Others (please specify)……

    Additional documents and information supplied (such as definition of a prohibited substance):

2. I agree to abide by the rules and protocol of this program as stipulated in the "AORC Standard Operating Protocol for Analytical Data Review (Phase II), Issue 02, 19 Dec 2019".

3. My contact details for all correspondence related to this request are:
    Address:……
    ……
    Email: …… Tel:……

4. My preferred route (e.g., courier or e-mail) and details (e.g., contact details of the designated recipient) for receiving the Confidential Report are:
    ……
    ……

5. I wish to exclude the following ADRB members (up to 3) from reviewing my submission:
    …… …… ……

6. Other remarks or requests:

Signed:…… Date:……

Disclaimer: A Data Review Panel of the AORC Analytical Data Review Board will conduct the requested review on the reported or proposed findings, analytical data and other information supplied by the initiator on an "as-is" basis. Accordingly, the Data Review Panel will not accept any responsibility for any inaccuracy or insufficiency of the information and data provided. The initiator also agrees to hold the AORC Analytical Data Review Board and the Data Review Panel harmless and shall indemnify the Data Review Panel against any loss, damages or costs suffered or incurred as a result of any claim or proceedings for incorrect or incomplete opinion relating to such review.

Appendix 2: Model Review Report (on AORC Letter Head)

CONFIDENTIAL

Date: _____

[Name]

[Organisation]

Dear _____

On [Date], the AORC Analytical Data Review Board (ADRB) received a request from [Name] to have the analytical data and reported / proposed findings associated with Sample Code [Sample no.] from [the name of authority] reviewed.

The findings reported / proposed were: ……

……

On [Date], the ADRB received the analytical data and relevant information, which have now been reviewed carefully by an independent Data Review Panel, comprising the following experienced and qualified racing chemists:

1.
2. and
3. as the Chair.

Based on the review, this Data Review Panel [either] endorses / does not endorse the reported / proposed findings [or] cannot form an opinion on the reported / proposed findings due to insufficient information provided. The Panel's view has been derived from a majority / unanimous opinion of the three Panel members.

Yours sincerely,

_____

[Name]

Chair of the Data Review Panel,
AORC Analytical Data Review Board

Disclaimer: The Data Review Panel of the AORC Analytical Data Review Board has conducted this requested review on the reported/proposed findings, analytical data and other information supplied by the initiator on an "as-is" basis. Accordingly, the Data Review Panel does not accept any responsibility for any inaccuracy or insufficiency of the information and data provided. The initiator also agrees to hold the AORC Analytical Data Review Board and the Data Review Panel harmless and shall indemnify the Data Review Panel against any loss, damages or costs suffered or incurred as a result of any claim or proceedings for incorrect or incomplete opinion relating to such review.