

AOAC International
Technical Division on Reference Materials

Process for Reference Material/ Method

Matching

October 26th, 2000

1. Introduction

Quality assurance of analytical measurements involves three aspects: use of validated methods, reference materials and proficiency testing, each of which is addressed in programs and activities of the AOAC International. Official Methods of Analysis, Peer-Verified Methods and Performance Tested Methods address the availability of collaboratively studied methods that have been verified to be capable of obtaining the results for which they are applicable. However, use of these validated methods by themselves does not guarantee that results will be correct. The methods have to be implemented and performed correctly. Verification of correct implementation and routine use of validated methods is best evaluated by proper incorporation and use of appropriate samples with known content of the measured analyte, i.e. reference materials.

This proposal describes a process for linking specific reference materials (RMs) from all over the world to specific official methods. This information could then be provided as a service to members of AOAC International and a potential source of income when non-AOAC members would like to access this information. The matching of suitable RMs to official methods of analysis offers many benefits to the scientific community. Many official methods do not indicate the scope of matrices to which the method can be applied. The compositional factors in foods that influence the results of an analysis are often complex and difficult to predict. The reference materials/ method matching (RM/MM) process provides assurance to the analyst that the selected RM will be a valuable tool to validate this method in their laboratory.

The process described in this proposal has been refined in the last two years using two trial RM/ method matches that required different approaches. The first trial involved an AACC certified food grade oat bran reference material matched to AOAC Methods 992.28 and 995.16. Much like the AOAC total dietary fiber procedure, the method defines this analyte. Because a study had already been performed comparing the results of the analysis of this RM using both methods, the data supporting this match were already available. The proposal outlined on the form designed for this process can be found in the Appendix to this document. This proposal has been evaluated and accepted by the RM/MM Committee, the General Referee for Commodity Foods, the Commodity Foods Committee and the Official Methods Board. Acceptance by the Official Methods Board was contingent upon the entire process being accepted by the Board of Directors. No objections were raised to this proposed match.

A second trial match involved a reference material from LGC (UK), a corn oil with added BHA and BHT. It was proposed that this RM be matched with AOAC Method 983.15, an HPLC method for quantitating these antioxidants. Unlike the first trial, no data were available to indicate how well this method worked with this RM. Volunteers were found to analyze the corn oil and generate additional recovery data. It was discovered that high recoveries of BHA (greater than 94%) were obtained with AOAC Method 983.15, but the recovery of BHT was less than 80%. The issue of whether a RM/MM can be made using recovery factors to obtain the assessed value was raised. At this point, the sponsor of this match is conferring with the Chairman of the Additives,

Beverages, and Food Process-Related Analytes Method Committee to determine how to proceed. While this match has not been successful to this point, it did provide added confidence that the review system will work properly and that these types of critical issues will be raised.

The subsequent pages describe the details of the RM/MM process. The individual RM/MM proposals will be taken through the process by the individual proposing the match with the guidance of the RM/MM Coordinator. The Coordinator is a volunteer position and will be charged with the responsibility of helping the individuals submitting proposals and tracking the proposals as they progress through the various stages of the process. Ms. Fatima Johnson has already agreed to fill the position of Program Coordinator. The end product of this effort could be a stand-alone document, a section of the OMA, or a site within the AOAC web site that is available to AOAC members. For non-AOAC members, the information could be accessed for a fee.

2. Reference Material/ Method Matching Process

2.1. Submitting a Reference Material/ Method Match

Anyone can initiate a request for a RM/MM. To initiate the formal process, the submitter must fill out the RM/MM Form to insure all of the required information is documented. The RM/MM Form is included in this document. This form includes a place to provide a full description of the RM proposed for the match, information on source and availability of the RM, and applicable data (and/or references) supporting the suitability of the RM for the Official Method it is to be matched with. The request is then submitted to the RM/MM Coordinator and the RM/MM Committee.

When it is necessary to make multiple copies of a proposal and distribute them to a committee, the submitter will be required to take on this responsibility.

2.2. Coordination of Reference Material/ Method Match Proposals

The RM/MM Coordinator, along with the submitter of the proposal, is the person that keeps the whole process moving. This is a volunteer position whose job it is to coordinate and track the proposals as they pass through the process and serve as a resource person for those initiating proposals.

As a rule of thumb, three weeks is a reasonable amount of time for a reviewer to read the proposed RM/MM and make a decision on its merits. The RM/MM Form has a place to enter a deadline for a decision on various steps of the process. In this manner, reviewers

know what is being asked when they receive the proposal. When this time frame is exceeded, it is the responsibility of the Program Coordinator to gently remind the late reviewers that the process needs to move on. The vast majority of this communication should be done by electronic mail so that the position of Program Coordinator does not become a financial burden to the volunteer.

2.3. Review Committee for Proposed Reference Material/ Method Matches

The RM/MM Committee consisting of the TDRM liaisons to each respective Official Methods Committee has been established. The Chair of this committee shall be appointed by the TDRM Executive Committee.

2.4. Review of Proposals for Reference Material/ Method Matches

A flow chart of the RM/MM process is presented in the attached figure. Once the submitter of a proposal to establish a RM/MM has filled out the RM/MM Form:

- 1) The Submitter will send the proposal to the RM/MM Coordinator (Program Coordinator) as well as distribute the proposal to the members of the RM/MM Committee. This will be the Program Coordinator's signal that the process has begun for that proposal and it will need to be tracked through the system. The Program Coordinator will keep a hard copy of each proposal on file.
- 2) The Chair of the RM/MM Committee will coordinate the review and submit the committee's recommendation regarding the RM/MM to the appropriate General Referee and the Program Coordinator. The Program Coordinator will keep the Submitter informed as to the progress of the proposal throughout the process. The Chair of the RM/MM Committee will be responsible for keeping a hard copy of all recommendations from the committee to assure adequate tracking and record keeping.
- 3) A recommendation to reject a RM/MM by 1/3 or more of the committee members will terminate the proposal with no appeal.
- 4) A recommendation in favor of proceeding with the match will result in the match proposal being forwarded by the RM/MM Chairman to the appropriate General Referee (GR) for a recommendation for inclusion in the Official Methods of Analysis or other chosen means of publication (See Section 2.5). The Program Coordinator will inform the Submitter of this progress.
- 5) A decision by the GR to reject the proposed match will terminate the proposal. This decision must be communicated to the Program Coordinator by the GR, who then informs the Submitter. This decision is subject to appeal to the RM/MM Committee and the respective Official Methods Committee. The Submitter has the responsibility of sending the proposal to the members of these committees for this appeal. The RM/MM Coordinator must be kept abreast of this action and can assist in identifying the proper individuals that will be involved.

- 6) A decision to recommend the proposed match will result in the proposal being forwarded by the GR to the respective Official Methods Committee. The Program Coordinator is informed of the progression.
- 7) A recommendation to reject a RM/MM by 1/3 or more of the committee members will terminate the proposal with no appeal. The GR must inform the Program Coordinator of this outcome, and this information is then passed on to the Submitter.
- 8) A recommendation in favor of proceeding with the RM/MM will result in the proposal being forwarded to the Official Methods Board (OMB) for final decision regarding publication. The Submitter with the assistance of the Program Coordinator will have the responsibility of getting the proposal to the appropriate individuals. A recommendation to reject a RM/MM by 1/3 or more of the OMB will terminate the proposal with no appeal.
- 9) A recommendation in favor of accepting the match proposal for publication will result in official matching of the Reference Material to the respective Official Method. Once accepted, the submitter will send the RM/MM Coordinator all critical documentation related to the approval of that RM/MM for the creation of a permanent record.

2.5. Publication Options for Reference Material/ Method Matches

1. Published as a free-standing guide “**Suggested Reference Materials for the Assurance of Quality Performance of AOAC International Official Methods of Analysis**”.
2. Published as a Chapter in OMA titled as above.
3. Published as an Appendix to OMA titled as above.
4. Published as part of the respective Official Method of Analysis (disadvantage of this option is the continual updating and removing of RMs).
5. Place on the TDRM web site.

Published information should include relevant data/references in the RM/MM Form format (text in standardized format is probably preferred over a spreadsheet because of ease of updating). It could also include a current list of RM suppliers. This publication could also include reproducibility data, accuracy data, traceability if applicable, sources, date of adoption of RM/MM pair and limitations, if any.

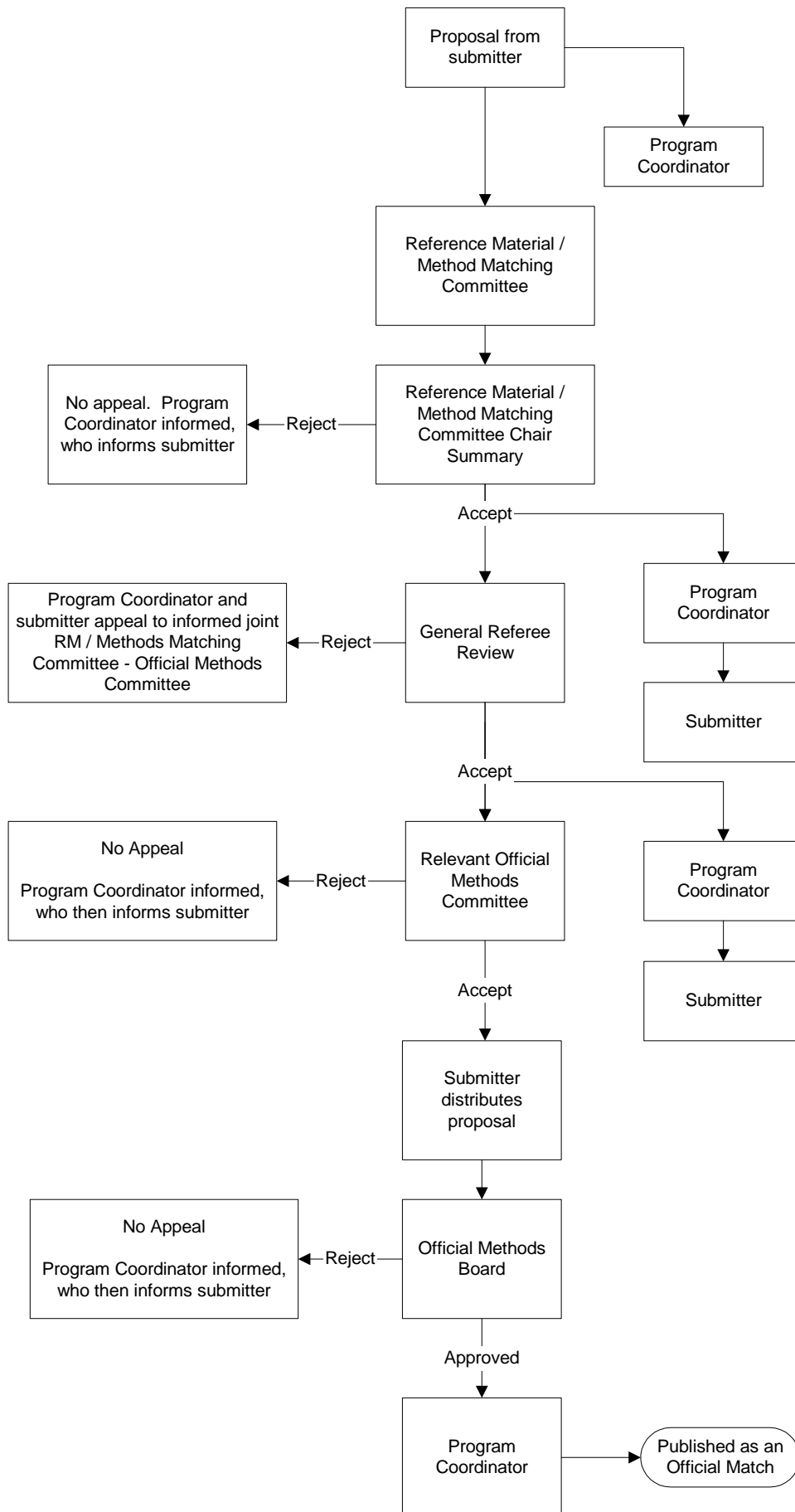
3. PROCEDURE FOR APPEAL ACTIONS

- 3.1. A decision by the GR to not recommend the proposed match for publication is subject to appeal to the RM/ MM Committee and the respective Official Methods Committee.
- 3.2 The appeal must be made in writing by the individual who submitted the original proposal. The documentation should include the original RM/ MM Form and a cover letter explaining why the rejection should be reversed.

4. PROCEDURE FOR REPEAL ACTIONS

- 4.1 The supplies of RMs are always limited and the organizations supplying these materials may choose to discontinue offering a particular RM. For this reason, a process for repealing a match must be in place.
- 4.2 Any individual who has information on the extinction of a reference material or a change in the certified value should notify the RM/MM Committee Chair in writing. The RM/MM Committee Chair will then verify the information with the RM supplier.
- 4.3 If the information is verified to be correct, the RM/MM Committee Chair will then instruct the Program Coordinator to make the change for the next update of the RM/MM publication.

PROCESS FOR ADOPTING REFERENCE MATERIAL / OFFICIAL METHOD MATCHES



AOAC INTERNATIONAL TERMS OF REFERENCE

I. NAME

Reference Material/ Method Matching Committee

II. MISSION:

To provide input and assist in the selection of appropriate official reference material/ method matches.

III. RESPONSIBILITIES

To review the proposals for RM/MM and vote on how appropriate these matches are.

To act as a communication link between the method committees and the Technical Division on Reference Materials.

To vote on appeals of proposals that have been rejected by the General Referee.

IV. COMPOSITION AND ORGANIZATION

The RM/MM Committee shall consist of a chair and ten members who serve as the liaisons between the Technical Division on Reference Materials and the ten respective method committees. The Chair of this committee will be appointed by the TDRM Executive Committee. The Chair of the RM/MM Committee will coordinate the review and submit the committee's recommendation regarding the RM/MM to the RM/MM Coordinator.

The members of the RM/MM Committee are appointed by the Chair of the RM/MM Committee. Inactive members of the committee may be replaced by the Chair after the committee member is informed of the impending change.

Additional subcommittees, task forces, and other appropriate subgroups may be appointed as the need arises.

V. STAFF LIAISON

The Executive Director shall assign a member of the staff to serve as the AOAC Staff Liaison. The Liaison communicates with the Program Coordinator to publish the successful RM/MM in the final compilation of matches.

VI. REVIEW SCHEDULE

Every three years.

VII. DATE ESTABLISHED

Established on a provisional basis in 1998.

AOAC INTERNATIONAL TERMS OF REFERENCE

I. NAME:
Program Coordinator

II. MISSION:

To help drive the process of getting RM/MM proposals through the review steps and track the status of each proposal.

III. RESPONSIBILITIES

The Program Coordinator is a volunteer who is charged with the responsibility of helping the individuals submitting proposals and tracking the proposals as they progress through the various stages of the RM/MM process. The Program Coordinator must have access to electronic mail so that they can communicate with others involved in the process in an economic manner.

The Program Coordinator receives a copy of every RM/MM proposal along with the RM/MM Chair. This is the signal for the Coordinator to begin tracking the progress of this proposal. The rule of thumb for this process is that each step should take a maximum of three weeks. If a reviewer has had a proposal longer than this time frame, the Coordinator should send an e-mail to that individual to politely ask the status of the review.

The Program Coordinator will communicate regularly with the Submitter of a RM/MM proposal to keep them informed of the progress of the review. If a proposal is rejected with no appeal, the Coordinator will pass on this information to the Submitter. If the proposal is rejected and an appeal is possible, the Coordinator will inform the Submitter of this possibility and assist the Submitter in distributing the proposal to the appropriate personnel, if desired. The Coordinator will also be knowledgeable in the composition of the various Method Committees and the Official Methods Board in order to assist the Submitter in distributing the proposal to the appropriate personnel.

The Coordinator will also be the record keeper for these proposals. When a RM/MM proposal has been through all of the review steps, the submitter turns over copies of all of the related documentation for the creation of a permanent file. The Program Coordinator also works closely with the AOAC Staff Liaison to get the approved RM/MM into the desired mode of publication.

IV. COMPOSITION AND ORGANIZATION

The Program Coordinator is a volunteer position. This individual works closely with the AOAC Staff Liaison and the RM/MM Committee Chair to coordinate the process.

V. REVIEW SCHEDULE

Every three years.

VI. DATE ESTABLISHED

Established on a provisional basis in 2000.