

Developing countries in pursuit of analytical quality control: the need for appropriate reference materials

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Summary. In a special session dedicated to problems of Analytical Quality Assurance (AQA) in Developing Countries (DC), the participants of BERM-5 had an opportunity to hear of the difficulties routinely encountered in many laboratories in these countries. Participants from Chile, China, Ghana, India, Korea, Malaysia, Philippines, Sri Lanka, and Thailand were invited to share the platform during this special session. The salient features of discussions that took place are summarized in this report and will not therefore be reported elsewhere.

Primary (certified) and secondary reference materials

The usefulness of Reference Materials (RM) in helping to provide AQA is globally recognized. As more analytical problems are identified, the need for new RMs, representing diverse matrices, will increase. For example, in the biological and environmental area alone, there is a vast opportunity and need to develop new types of Analytical Quality Control (AQC) materials.

Basically AQC materials can be classified as Primary or Secondary RMs. Primary Certified Reference Materials (CRMs) are generally those that are issued and certified by established agencies such as the National Institute of Standards and Technology (NIST) in the United States. These are materials which are prepared under stringent conditions and are carefully characterized before certification. NIST materials are internationally recognized as Standard Reference Materials (SRM). Secondary RMs are generally those which are prepared either as precursors of new types of CRMs, or to aid solution of a specific measurement problem. The existing CRMs often serve as AQC materials in characterizing the secondary RMs. In some cases the secondary RMs are prepared in small quantities for use as in-house RMs.

The preparation and certification of primary CRMs is expensive and time consuming. It also requires a high degree of expertise. These types of RMs are not intended for use as routine quality assurance (QA) materials and therefore, should be used with discretion. Their ideal use is foreseen when a new analytical method is established, when changes are introduced to an existing method, and for periodic check

of the analytical performance of a laboratory. Good quality secondary RMs can satisfactorily fulfil the normal requirements of QA of an analytical scheme; frequent use of such QA materials should be encouraged. An added advantage is that secondary RMs with specific matrices in required quantities can be prepared to meet needs either at a project level, or at a level to suit national or regional requirements. It is important to be able to prepare a secondary RM matrix that closely resembles the real world sample; this is very relevant to the requirements for specific types of RMs in developing countries. Well characterized secondary RMs, as working QA materials, are sufficient for a variety of purposes, including development of QC charts to monitor laboratory performance.

Developing countries

With few exceptions (e.g. China and Korea in some areas), many laboratories in developing countries are facing numerous limitations to their efforts to introduce adequate AQC procedures. These include inadequacy of laboratory facilities; difficulties in gaining access to published information; and paucity of suitable RMs for testing and improving analytical performance. Concerning RMs, the ensuing discussions clearly raised questions about the demand for RMs, the ways and means of acquiring RMs, and their proper use. There are no easy solutions to these problems.

The participants from developing countries frequently expressed the opinion that lack of resources to buy primary RMs (in some cases problems are linked to availability of hard currency) was the reason for not using them. Some of these problems can be solved by use of a secondary RM, but many developing countries do not have the expertise to prepare such QA materials. In cases where preparation of secondary RMs is feasible, the analytical expertise is often not available. Therefore the participants requested help to overcome some of the technical and scientific aspects of preparing secondary RMs.

Developing of regional programs

Following the formal presentation by the speakers of this special session, the discussion turned to the need for initiating regional programs. In this context the initiative of the newly formed Asian Society for Reference Materials (ASREM) was cited. Recognizing the QC problems faced by

laboratories in developing countries and to promote regional self-reliance in preparing secondary RMs, ASREM is striving to provide technical guidance and analytical help through a novel approach. The goal is to propagate proper use of primary RMs (i.e. certified and standard RMs issued by established agencies) for the preparation and comparison of secondary RMs needed by a particular country (or group of countries) for use in normal AQC measures. ASREM, as a discussion platform, is also exploring existing avenues to bring together participants from developing countries for workshop-like discussions related to AQC.

A group of representatives from several Asian countries have joined ASREM (identified as the user group). A second group, consisting of volunteer analytical scientists from both developed and developing countries, well experienced in the development and analysis of RMs has also been assembled (identified as the expertise assistance group). Members from the user group are encouraged to identify representative RMs, and take the lead in preparing a designated RM in one of the laboratories. The ASREM expert analyst group will assist by providing scientific and technical guidance for preparation and characterization of the QA material. If the RM is homogeneous and qualifies for recommendation as reference matrix with suitable concentration levels for some analytes, this material will then be available for distribution (at a nominal charge) among members of the user group. Similarly the burden of preparing a second material would fall on another member of the user group, thus making a second material available among the participating countries. This approach avoids duplication in developing a particular RM. Initially efforts in the area of food analysis have resulted in the preparation of ASREM-1 (a cereal-based children's food matrix with a supplemented level of biominerals) with the laboratory facility assistance of Central Food Technology Research Institute in Mysore, India. This material is currently being tested for homogeneity.

Suggestions for improvements

Almost all the participants were of the opinion that the demand for RMs is very great in developing countries. To acquire RMs from existing sources, the possibility of mobilizing resources (through voluntary and international channels) and procuring selected QA materials for distribution to developing countries was discussed as one possibility. However it was readily recognized that such a move can only be a temporary solution, besides being predictably inadequate. For example, the existing RMs seldom match the specific matrix requirements faced by the laboratories in developing countries. Alternatively it was suggested that it would

be of great benefit to all developing countries to initiate the following activities: improved accessibility to published information on QA materials and practices; training of staff personnel in AQC procedures; mobilizing technical assistance for providing guidance in preparing secondary RMs (in-house RMs); and identifying selected laboratories to act as Regional Analytical Reference Facilities. There was consensus that these measures are the keys for a lasting solution.

In seeking specific solutions to the problems listed above, the discussions centered on the question of improved accessibility to published information (e.g. existing RMs, their merits and disadvantages, the gaps in RM profiles and the need for new ones). Current efforts to address this problem through existing RM compilations (e.g. IAEA/RL/128, Vienna, 1990), and RM databases (e.g. COMAR); and by the on-going efforts of the International Standards Organization (ISO) Reference Materials Committee (REMCO) and the United Nations Environmental Protection (UNEP) Harmonization of Environmental Measurements (HEM) programs were noted. Several participants strongly urged that expanding the scope of the AQC training assistance which institutions such as the International Atomic Energy Agency are currently providing should be very beneficial. Similarly it was emphasized that starting new Regional Programs to provide technical assistance and practical training for the preparation of secondary RMs is essential. It would be helpful to identify one or two laboratories in a region and to strengthen their technical base so that they can take over the role of Reference Laboratories (RL). These RLs should be able to evaluate the performance of the other laboratories in the region which need AQC help and act as a local training center.

Since the basic concern of ASREM is a general reflection of the problems faced by many developing countries, it will be possible to widen the base of ASREM to include all developing countries if there is an integrated response from different global regions e.g. Africa and South America. Scientists in developing countries are encouraged to participate in the activities of ASREM. Efforts to locate a formal office for ASREM in the Asian region are under way. In the meanwhile correspondence on this subject may be addressed to the attention of the author of this report (Dr. G. V. Iyengar) at the address cited above.

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