CHAPTER IV

DATA QUALITY MANAGEMENT

A. DATA REQUIREMENTS AND PROCEDURES

1. Intended Use of Data

The UGLCC Study's main objectives were to assess the current status of the ecosystem and recommend remedial action where necessary. Parameters were selected for study based on historical problems in the various study areas and to provide information on a range of chemicals with different properties. Analytical methods for most of the study parameters are well established. The only exception to this was the analysis of trace organics at ambient concentrations in water. For the most part, only research laboratories have the capability to perform these analyses because of the low detection limits (parts per trillion) required.

The data generated for the study needed to be of sufficient quality to provide the approximate concentrations of the study parameters in the various media so that these concentrations could be related to ecosystem objectives. The data also needed to be of sufficient quality to show whether a particular study area was a net source or sink for the study parameter. The UGLCC Study was not intended to provide accurate loadings of the contaminants to the system or precise concentrations in all media; however, estimates of loadings and concentrations permit relative comparisons between contaminant sources.

A secondary study objective was to identify additional toxic contaminants that could be causing problems in the study areas. Thus, the laboratories must be able to identify the presence of these contaminants and to estimate their approximate concentration in the media analyzed.

2. Field and Laboratory Procedures

Sample collection procedures followed by all agencies are well documented in the principal investigator reports. For the most part, sampling was conducted according to established protocols. For specialized sampling, such as ambient waters, thoroughly tested published procedures were used. Water and effluent samples were stored at 4^0C with the addition of appropriate preservatives (for example, acid for metal analyses). Sediment and biota samples were kept frozen until analysis.

Samples of effluent for the point source survey were 24 hour (U.S.) or 3 to 6 day (Canada) composites. Most other samples collected were grab samples. The samples collected were appropriate to address the objectives of the study. For all studies the number of samples collected was limited.

Field blanks and replicates comprised over 10% of the analytical output of the study. In general, most parameters were not detected in the field blanks. In most cases the percent deviation between field replicates was less than 20%.

U.S.EPA methods were used by most laboratories for the analyses. These methods specify frequencies of calibration, blanks, spikes, duplicates, and surrogate spikes. The achievement of lower detection limits by some research laboratories required the use of large volume samples (up to 200 litres), larger than are specified in the U.S.EPA methods. Proportionally larger volumes of extraction solvents were used for these samples. The final determinations were usually by U.S.EPA or comparable methodology.

B. DATA QUALITY MANAGEMENT

The experience of earlier international multi-media studies in the Great Lakes Basin, particularly the Niagara River Toxic Committee Report (NRTC) (1), demonstrated the need for a careful and systematic program to ensure data quality and the utility of analytical results. Those involved in the NRTC Study strongly recommended the establishment of a data quality management program as one of the first actions of the Upper Great Lakes Connecting Channels Study.

The earlier studies found that commercial, government, and academic laboratories use different analytical methods, instruments, standards, levels of detection and reporting formats. Without external checks, there are no means to ensure that data generated by two or more laboratories would generate comparable data. Furthermore, agreement had to be reached among representatives from agencies having differing missions, goals and study requirements for a common protocol or strategy for data quality management. As part of such a strategy, the Management Committee agreed that, wherever possible, the number of laboratories providing analytical support would be minimized and laboratory facilities would be shared by the agencies in the study. This was an important step in minimizing potential variability in the data.

1. Activities

The Management Committee formed a Quality Management Workgroup (QMWG) from the agencies providing field and analytical service support. Consulting personnel experienced in statistical design and data quality analyses were also identified. The terms of reference for the Workgoup were as follows:

1) establish a quality management system for the UGLCC Study;

2) review and evaluate the suitability, completeness and competence of individual project quality assurance plans;

3) recommend quality assurance requirements for sampling, sample handling, analysis, management of project data and quality control data;

4) compile, review and report on the appropriateness of analytical and field protocols identified in the Quality Assurance Project Plan, as they became available;

5) provide guidance to other workgroups in the analysis and use of historical data as required by the Activities Integration Committee;

6) require and review periodic Quality Assurance (QA) reports from the individual workgroups; and

7) review draft project reports with respect to QA issues.

Throughout the Study, the QMWG maintained close contact with the Management Committee and the Activities Integration Committee. The QMWG Chairman or a representative participated in their meetings and provided verbal and written briefings on issues as they arose. A data quality management strategy was agreed upon (2). This included a project data quality plan document which was given to each project leader. This project plan was submitted to the workgroup by the principal investigators and was then reviewed by the QMWG. The review assessed the proposed project quality assurance and quality control procedures as well as, where feasible, the statistical design of the project. The data quality management strategy also included a series of thirteen interlaboratory "round robins" consisting of the analyses of "standardized" samples of blind concentration and composition. The results of the studies were provided to the Activities Integration Committee and the Management Committee such that corrective action could be taken as necessary.

It must be recognized that each agency has its own criteria for determining suitable field and laboratory procedures. In most cases these are chosen to meet the agencies' specific mandates. Within the time available to UGLCCS, it was not possible, and probably not advisable, to institute method changes to achieve standard procedures among the participants. The most that could be achieved was to:

a) encourage good project planning, including all necessary quality assurance activity;

b) encourage documentation of methods; and

c) initiate a limited number of round-robins, using such standards as were readily available to evaluate the accuracy of participating laboratories.

It was known from the start that many of the field techniques employed for sampling and sample handling were relatively untested, especially for the organic constituents, because they were part of exploratory research programs. There were questions about analytical procedures that might be employed, in terms of their ability to identify and quantify the many chemical constituents of interest in the water, sediment, biota and effluent samples. These issues were recognized early on by the other workgroups, and were the topic of much discussion.

Some difficulty was anticipated because the different jurisdictions employed a variety of control practices to a greater or lesser degree. There was concern that existing field and laboratory methods might not include the quality control and quality assurance protocols needed to verify proper application, and to document the level of quality achieved for UGLCCS. In the past, the impact of ongoing laboratory quality control activity in all these areas had been limited by the absence of a "top-down" management system to define responsibilities and ensure adequate documentation. Hence, Management Committee formally endorsed a modified U.S.EPA guidance document (3) as the basis for a quality assurance project plan to be filed for each project for initiating a verifiable QA process. The documentation and procedures required by the UGLCCS Project Plan guidance document is shown in the workgroup report (2).

2. Project Plan Review Findings

The magnitude of the study required intensive effort on the part of all workgroup chairmen to keep projects on track. Ultimately, most projects were implemented without adequate prior QA review, however, laboratory support for one project often provided data to serve other activities. A total of 30 project plans (out of 170 projects) were received from the workgroups, the majority dealing with biota and sediment. The workgroup QA project plans were distributed as received for review by teams of one or two QMWG members based on their expertise in field, laboratory, QA, sampling design, and related statistical factors. Project plans tended to follow the guidelines but were not necessarily complete in defining or justifying their methodology, data quality needs, or relationships to methodologies used by the other related projects.

Many project leaders had difficulty in providing detailed up-to-date descriptions of their field, laboratory or QA/QC procedures. This is not due to the absence of defined procedures, nor the lack of appropriate QA/QC activities: but, simply because the necessary documentation was not readily available. Some provided excellent documentation in one or more areas; but, there was not always a clear link between project needs and the specific technology used. Not all plans were evaluated for sampling design or other statistical aspects because some projects were essentially exploratory or were already in progress or even completed.

In general, the concept of a centralized quality assurance review on a project by project basis was new to many of the participants. Most project leaders had never experienced such a responsibility for providing the type of detail required in the QA review protocol. The normal relationship for most project leaders to their supporting analytical laboratories was that of a

client to a service organization. As a result, significant difficulty was encountered in providing not only the requested detail but the type of material to be provided, its actual relevance to the UGLCCS, and the volume of material that was needed for review. Due to the large scope of the project, not all the members of the QMWG were fully familiar with specific laboratory practices, the analytical methods or the statistical methodology used by various organizations.

Delays in QA project plan reporting were encountered due to incomplete reports and the large volume of background information that had to be gathered, compiled and reviewed by disparate groups of professional individuals in both the field study and the QA review process.

C. INTERLABORATORY PERFORMANCE EVALUATIONS

1. Background

Field sampling procedures, sample handling and preservation, delays initiating analyses, sample matrix effects on the analytical process all affect data quality. However, there is no question that the analytical measurement is especially critical to the validity of project data. Traditionally, the single most serious source of variation between results from different laboratories is the control of standards and the instrument calibration process. For this reason the QMWG agreed to place most emphasis on the distribution of a series of check standards covering all of the UGLCCS parameters for which checks were available.

2. Approach

The QMWG recommended that interlaboratory performance evaluation quality control studies should be designed and carried out at least three times with test materials containing all constituents at low, medium, and high concentrations. Such studies would be presented and evaluated before, during and at the close of all analytical and field related activities. These studies were carried out in conjunction with a quality management strategy and in concert with an interagency split-sample program, and allowed management full control and assurance of data quality for the UGLCC Study. It was evident that this comprehensive program could not be issued in a timely manner (2). A reduced program was adopted that involved less frequent studies, use of only standard solutions, surrogate spikes and a limited number of natural reference materials.

The samples for the thirteen studies listed in Table IV-1 were prepared and distributed to twenty-six laboratories in different portions of the "round robins". The laboratories were requested to analyze for 36 inorganic and 50 organic parameters (see Table IV-1). Three reports for each interlaboratory study were generated by the QMWG:

a) a raw data summary to the participants (for verification);

b) a final data summary when the study was closed; and

c) a final laboratory performance evaluation report.

In addition, 3 status reports were prepared to advise MC and AIC chairpersons on extreme results. Extreme results were those results that deviated significantly from target values. Brief advisory reports reviewing the results of each interlaboratory performance assessment study from the QMWG to the MC/AIC, were

TABLE IV - 1

QC study parameters for interlaboratory performance evaluation of UGLCCS QC studies.

Study	Test Samples	Parameters	Substrate
QM-1	4 ampuls	Aroclors	std solutions
	4 ampuls	O.C. Insecticides*	std solutions
	4 ampuls	Chlorinated Hydrocarbons**	std solutions
QM-2	4 ampuls	16 PAHs	std solutions
QM-3	5 sediments	10 Metals	sediment CRM or RM
QM-4	4 waters	23 Major Ions & Nutrients	water CRM
QM-5	4 waters	7 Metals	water CRM
QM-6	4 sediments	Chlorinated Hydrocarbons**	sediment CRM or RM
	2 ampuls	Chlorinated Hydrocarbons**	std solutions
QM-7	2 ampuls	Aroclors	std solutions
	2 ampuls	Chlorinated Hydrocarbons**	std solutions
	4 ampuls	Aroclors & Chlorinated Hydrocarbons**	spiking solutions & natural water
QM-8	4 ampuls	Chlorinated Insecticides*	std solution
	4 ampuls	Chlorinated Insecticides*	spiking solutions & natural water
QM-9	4 waters	Mercury	water RM
QM-10	2 ampuls	16 PAHs	std solution
	4 ampuls	15 PAHs	spiking solutions & natural water
QM-11	4 waters	Cyanide	water RM
QM-12	4 waters	Total Phenol	water RM
QM-13	2 ampuls	5 Chlorophenols	std solutions
	2 oils		fish oils
	2 tissues		fish tissues

* HCB, (alpha, gamma) BHC' Mirex, pp'- DDE' pp - DDD, pp'-DDT, heptachlor epoxide, dieldrin, (alpha, gamma) Chlordane, oxychlordane.

** (1, 4, 1, 3, 1, 2) dichlorobenzene, (1, 3, 5, 1, 2, 4, 1, 2, 3) trichlorobenzene (1, 2, 4, 5, 1, 2, 3, 4) tetrachlorobenzene, pentachlorobenzene, hexachlorobenzene, hexachlorobutadiene, hexachloroethane, octachlorostyrene.

used by the UGLCCS management to implement the QA management strategy and to ensure that appropriate corrective action could be taken.

D. UGLCCS QUALITY ASSURANCE RESULTS

1. Percent Recoveries

The following results have been summarized from QMWG integrated reports evaluating interlaboratory performance for organics (4) and trace metals (5). As part of the QMWG recommendation for a QA/QC program for UGLCCS, values determined for samples should fall within a window of +/-25% of the design values.

Trace Metals

Figures IV-1 and IV-2 present graphically condensed results of the range and average values of percent recoveries of interlaboratory medians for all elements analyzed and all samples reported in sediments and waters, respectively.

For the sediment samples analyzed in QM-3, results for seven out of 10 elements, namely Pb, Zn, Hg, Cu, Ni, Co and Fe, were satisfactory because average recoveries for all samples tested were within +/-25% of the design values and the ranges of recoveries for all samples were within +/-25% of the design values. The performance for Cd and Se in these sediment samples were also satisfactory with average recoveries for all samples falling within +/-25% of the design values. However, the ranges of recoveries for all samples tested showed wide variations and fell outside the limits (+/-25%) of the design values (Figure IV-1). The interlaboratory results for Cr were less satisfactory with average recovery for all samples exceeding +/-25% of the design value. This was assumed to be due to incomplete digestion of the sediment samples.

For the water samples analyzed in QM-5 and QM-9 as shown in Figure IV-2, the interlaboratory comparability was excellent. All seven elements, (Cd, Pb, Zn, Cu, Ni, Co and Fe), determined in QM-5 and Hg in QM-9 were satisfactory with the ranges and averages of interlaboratory medians for all samples within +/-25% of the design values. The ranges of recoveries among test samples had wider variations for Zn and Hg than those obtained for the remaining elements.

Overall, comparing the precision of interlaboratory results for sediment and water samples, the less scattered results among test samples were obtained for water samples than those obtained for sediment samples, except for Hg. The wider variations of relative standard deviation (RSD) for Hg among test samples for water samples as compared with those for sediment samples, perhaps, was attributed to the lower concentrations of Hg in these water samples. In general, the interlaboratory comparability for the accuracy and precision of trace metals in sediment and water samples was satisfactory in most cases.

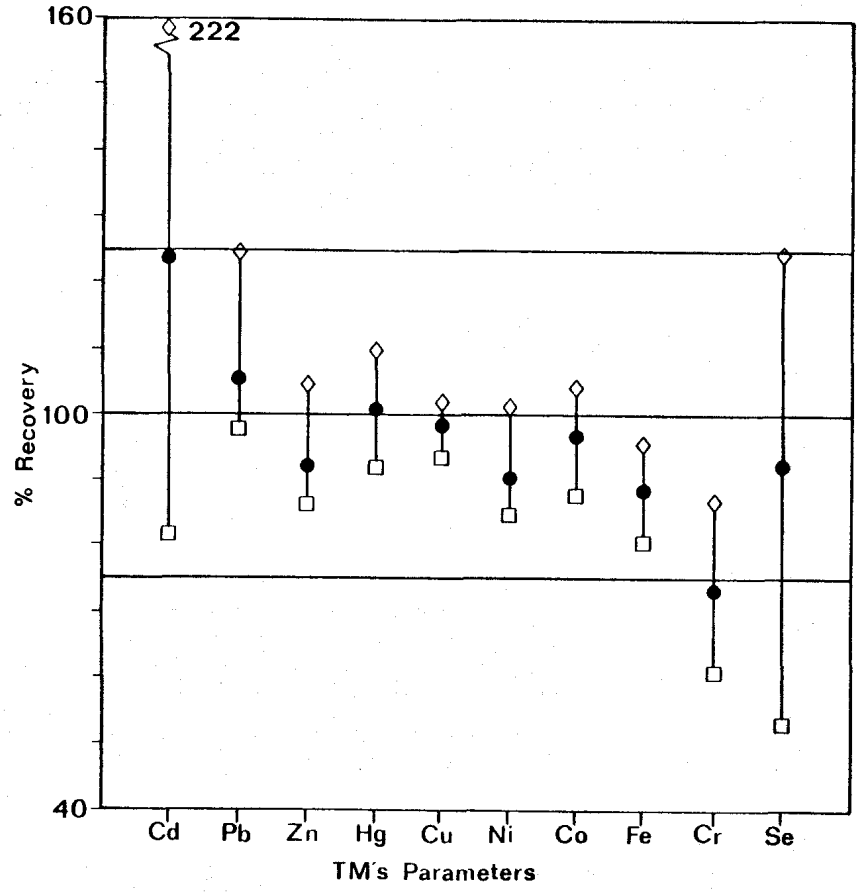

FIGURE IV-1. Percent recovery for trace metals (sediments).

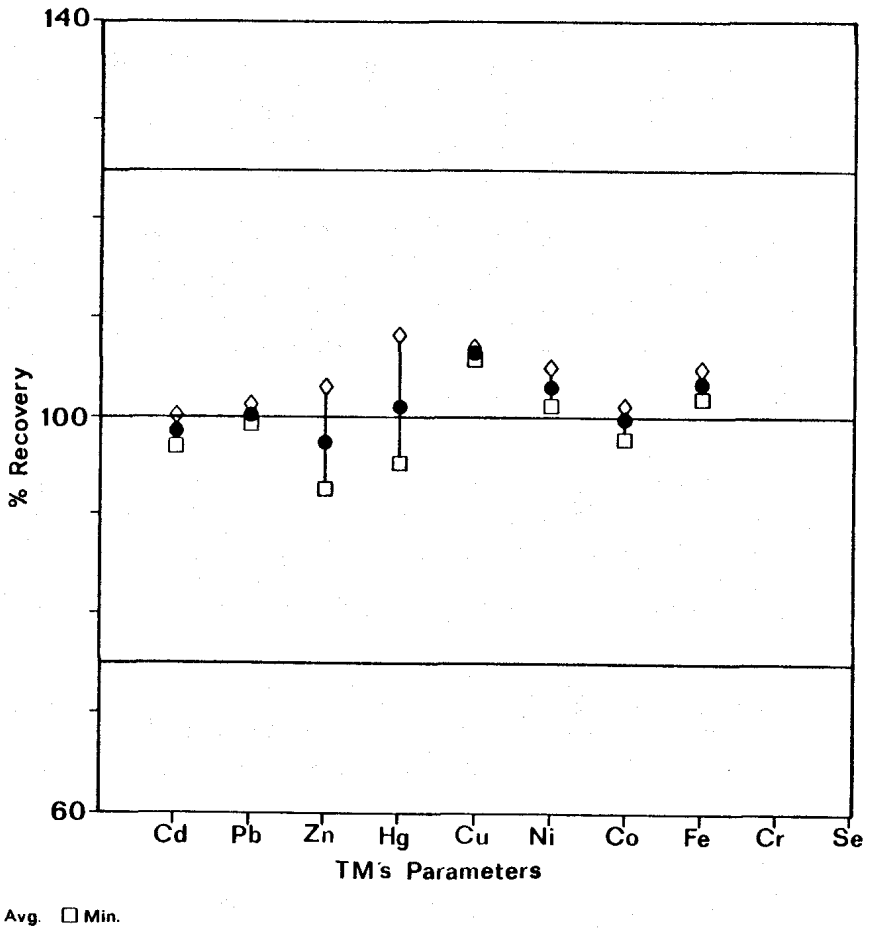

FIGURE IV-2. Percent recovery for trace metals (waters).

Organic Parameters

i) OCs (Organochlorines)

The QMWG had set results within +/-25% of the design values for organic parameters as satisfactory. The agreement of interlaboratory medians for organochlorines was excellent. The results for all the samples were satisfactory within +/-25% of the design values for all OC parameters except sample 108 in QM-1 for p,p-DDD.

In order to detect the bias of interlaboratory results, the range and average of interlaboratory medians for all OC parameters in various studies were summarized. Figure IV-3 presents condensed results of average recoveries of interlaboratory medians for all samples in various studies. As can be seen from this figure, the interlaboratory results were compatable and satisfactory for all OC parameters in ampules of both QM-1 and QM-8. Furthermore, the interlaboratory results in QM-8 were more accurate than those in QM-1 for all OC parameters in most cases.

The percent average recoveries of OCs in spiked water samples in QM-8 were less accurate as compared with ampule samples in both QM-1 and QM-8 studies. However, the interlaboratory results for all OCs in QM-8 were still satisfactory within +/-25% of design values except for HCB.

ii) PCBs (Polychlorinated Biphenyls)

The agreement of interlaboratory medians in PCB test samples was excellent and percent recoveries of interlaboratory results were all satisfactory (within +/-25% of the design values) in both studies. The accuracy of interlaboratory comparability for PCBs in ampules and spiked water was very satisfactory in both studies.

iii) CHs (Chlorinated Hydrocarbons)

The results of CH analyses suggest that interlaboratory performance by participating laboratories, in most cases, improved in QM-6 and QM-7 as compared with the earlier QM-1 using some identical samples in various studies. In QM-1, some CHs were different by more than +/-25% of the design values; while all CHs were satisfactory within +/-25% of the design value in sample 606 of QM-6 and samples 703 and 704 of QM-7. These results suggest that the earlier interlaboratory studies helped the participating laboratories correct their internal quality control and that the quality of the test samples used for these evaluations was verified.

In order to evaluate the interlaboratory comparability, the range and average of percent recoveries of interlaboratory medians in

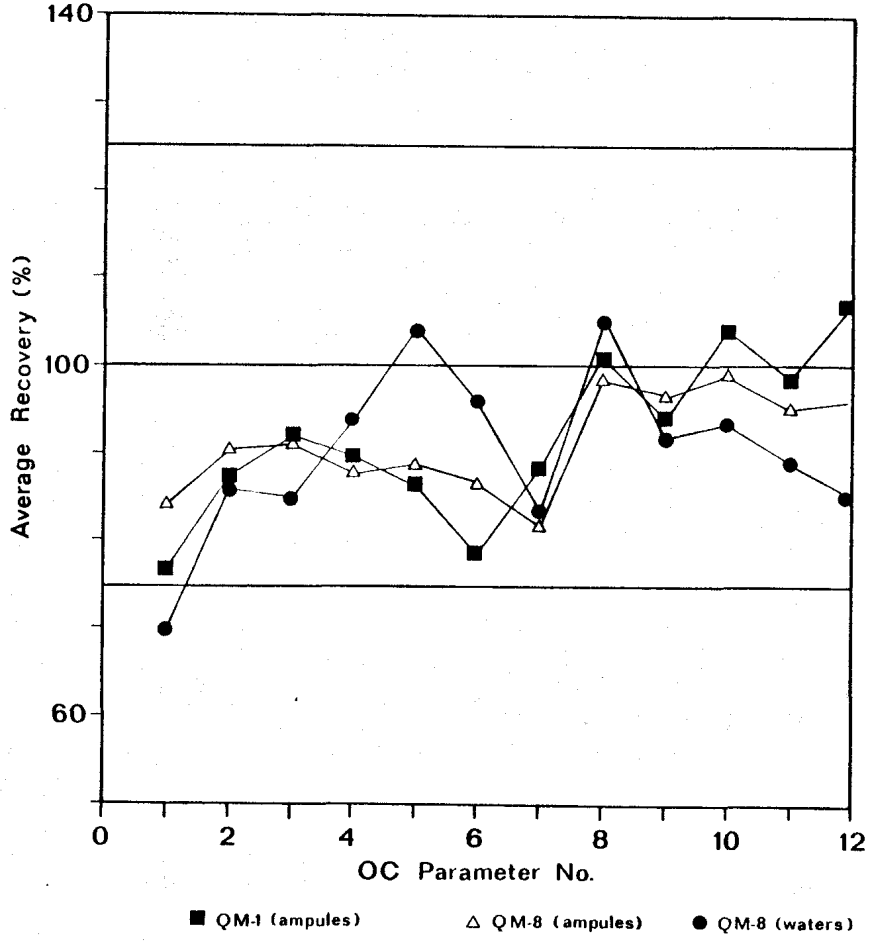

FIGURE IV-3. Average recovery (%) for OC's (various studies).

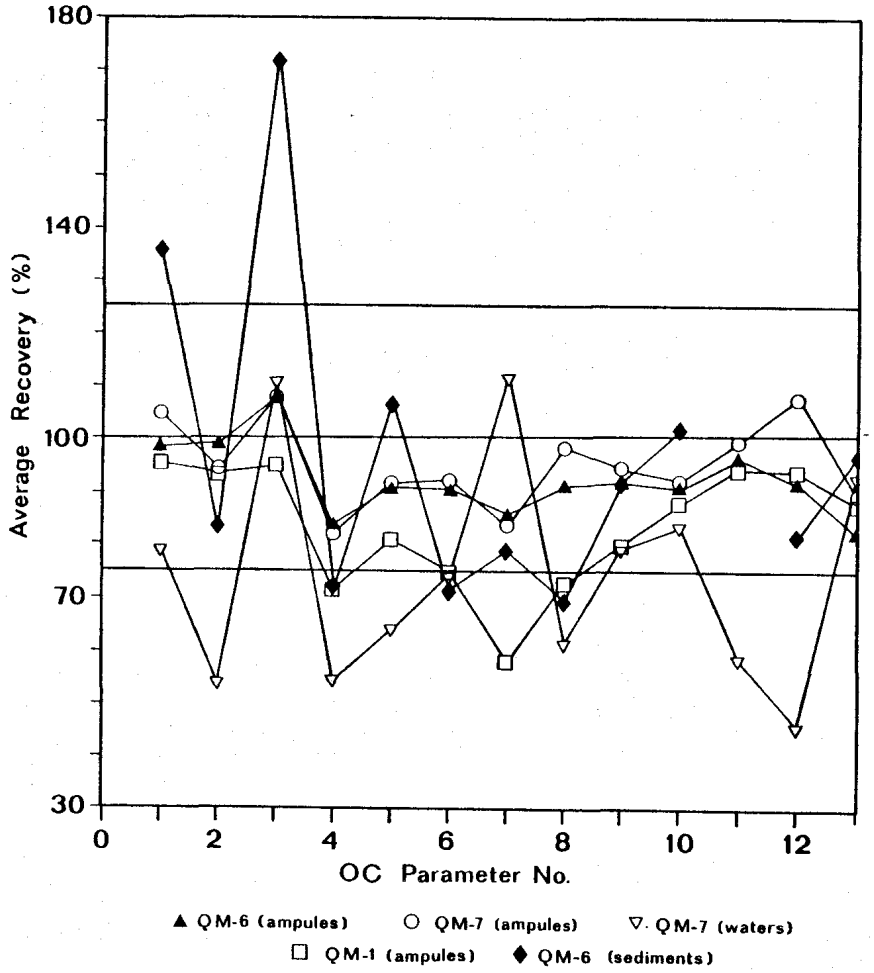

FIGURE IV-4. Average recovery (%) for CH's (various studies).

various studies were summarized. Condensed results of average recoveries of interlaboratory medians for all 13 CH parameters are shown in Figure IV-4.

As expected, the interlaboratory results for spiked waters (QM-7) and sediments (QM-6) were less satisfactory as compared with the ampule samples (QM-1, QM-6 and QM-7). Overall, only six out of thirteen parameters (1,4-DCB; 1,2-DCB; 1,2,4,5-TeCB; PeCB; HCB; and OCS) in water samples (QM-7) were within +/-25% of the design values. The performance of spiked waters for CHs (QM-7) was less satisfactory as compared with those of spiked waters for OCs (QM-8) and PCBs (QM-7). However, the interlaboratory results for sediments were less satisfactory as compared with ampule samples but were better than those in spiked water. Overall, seven out of 12 CH parameters were satisfactory within +/-25% of design values (HCE was not evaluated since a reference value was not available).

Poor quantitative recoveries of CHs from spiked waters were expected because of the volatility of most CHs, resulting in evaporative losses. In addition, the high water solubilities of some CHs also cause poor extraction recoveries.

iv) PAHs (Polycyclic Aromatic Hydrocarbons)

Figure IV-5 presents graphically the condensed results of percent average recovery of interlaboratory medians for all 16 PAHs in various studies. For the ampule samples, the interlaboratory results were satisfactory within +/-25% of the design values in most cases. Only three out of 16 parameters (fluorene, phenanthrene and chrysene) varied by more than +/-25% of the design value in QM-2 while all 15 PAH parameters were satisfactory within +/-25% of design values in QM-10. The performance of PAHs showed a significant improvement in QM-10 as compared with the earlier QM-2.

2. Overall Laboratory Performance

Acceptance Criteria

The key to administering information involving the laboratory performance data is the selection of acceptance criteria. The overall performance evaluation in this integrated report is based on percent biased of parameters analyzed and percent flagged of results reported. For the flags, the number of results reported by each laboratory excluding those with "ND" (not detected), "NS" (not separated; 2 parameters co-eluted), and "LT" (less than) codes, sum of results flagged with VH, H, L or VL, (very high, high, low, very low) for all parameters, and the percentages of results flagged were calculated. In addition, values less than detection that were flagged were included in the calculation of

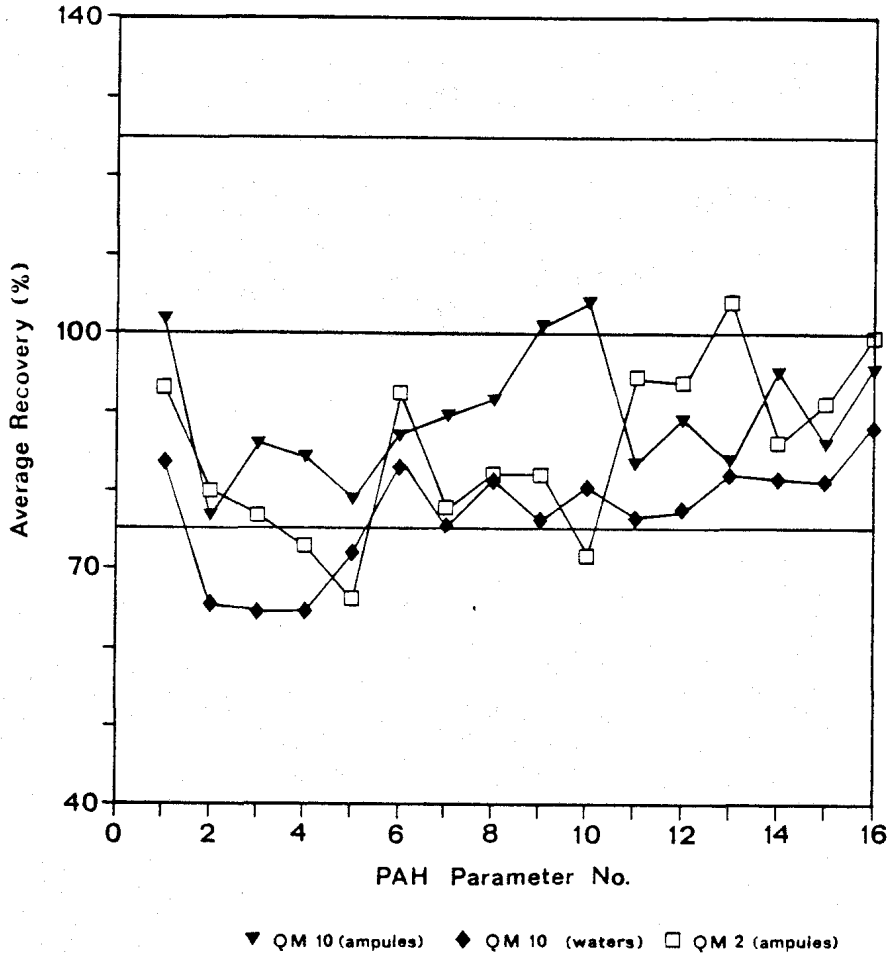

FIGURE VI-5. Average recovery (%) for PAH's (various studies).

the percent flagged. Similarly for the bias, the number of parameters analyzed by each laboratory, the sum of parameters biased with VH, H, L, VL based on average recovery for each set of samples and the percent of parameters biased were calculated. Note that the H and L parameters biased were counted as half of a VH or VL parameter.

To simplify the overall assessment of laboratory performance in various studies, the average of percent biased and percent flagged is calculated. The criteria or performance index provides a simple way to compare laboratory performance in various studies as shown below:

Average of Percent Biased and Percent Flagged	Comments
< 25%	Satisfactory (A)
26-50%	Moderate (B)
> 51%	Poor (C)

Trace Metals

Most laboratories provided consistent and satisfactory results for the interlaboratory studies for trace metals (5).

Organic Parameters

i) OCs

For the laboratory performance of OCs in various studies, few laboratories have achieved consistency for producing satisfactory results for both ampule and spiked water samples. Some other participating laboratories also produced satisfactory results but only participated in one study: either QM-1 for ampules or QM-8 for both ampules and spiked waters. However, for these OC interlaboratory studies, only one laboratory produced inconsistent and rather poor results for OCs in both ampules and spiked waters.

ii) PCBs

Three laboratories achieved consistency for producing satisfactory results for PCBs in both ampules and spiked waters. Although the PCB results for ampules were satisfactorily generated

by all participating laboratories in most cases, poor results for spiked waters were produced by several laboratories. It was obvious that less satisfactory results for spiked waters were attributed to sample preparation involved with extraction, concentration and clean-up steps because the results for ampules were satisfactory within +/-25% of design values by all participating laboratories.

iii) CHs

The laboratory performance for CHs in various studies was less satisfactory as compared with those obtained for OCs and PCBs. Only one laboratory, which analyzed all the samples provided and most parameters requested, achieved the consistency for satisfactory results in all matrices (ampules, waters and sediments). On the other hand, there were more poor results generated by participating laboratories in either matrices in these CH interlaboratory studies than for other parameters.

iv) PAHs

Only one laboratory achieved the consistency for producing satisfactory results for PAHs in both ampules and spiked waters. However, less than satisfactory results were generated by only two laboratories in either ampules or spiked waters. The performance of one laboratory in QM-10 was very satisfactory for both ampules and spiked water as compared with that obtained in QM-2. This extensive improvement for this laboratory has demonstrated that the impact of these interlaboratory studies was very valuable in assisting participating laboratories to correct their internal QA/QC problems.

E. FINDINGS AND CONCLUSIONS

It is difficult to summarize the performance of laboratories because data quality varies with each parameter, matrix, and laboratory as well as over time. Furthermore, the acceptability of data for each laboratory depends on project objectives. In general, the large service laboratories performed consistently better than the smaller service laboratories and research laboratories did not perform as well as the routine laboratories.

It must be stressed that the QC samples in the interlaboratory performance evaluation studies for UGLCCS are generally easier to analyze than actual field samples. Most of these quality assurance samples were standard solutions at reasonably high concentrations and did not require special preparation. It is also recognized that many laboratories took extra care and performed repetitive analysis when dealing with the QC samples. Therefore, unsatisfactory performance in these interlaboratory studies may indicate a poorer quality of data for real samples in routine analysis.

The impact of these interlaboratory studies on laboratory operations is illustrated by a couple of examples. A large contract laboratory was identified as having severe analytical problems in several performance evaluation studies partly due to ineffective in-house QC. The laboratory took corrective actions. The data quality for one type of parameter (PAHs), when subsequently re-evaluated, drastically improved. Three research laboratories and one large routine laboratory on separate occasions stated that the interlaboratory performance evaluation studies induced them to re-examine instrument calibration and the accuracy of the standards for chlorophenols, chlorobenzenes, PCBs and octachlorostyrene. Consequently, the analyst discovered poor in-house standards and improper calibration. Without these interlaboratory test samples, these laboratories would not have been aware of their internal biases.

The timeliness of QMWG follow-up on the findings of these studies was significantly impaired by the slow response of some of the participating laboratories. The reporting deadlines were frequently exceeded due to internal schedule conflicts. The actual number of laboratories providing results for any given test parameter depended on whether their UGLCCS project included that parameter. Hence, where severe scatter between laboratories was observed, it was not possible to decide whether this reflected poor control, or just the current "state of the art".

Many of the check samples were standards, and one would expect reasonably good recoveries and precision. In fact, for many of the organic tests, although a given lab frequently reported very similar results on the duplicate samples, the spread of results across labs was quite large. There is a definite need for an

intensified effort by organic analysts for better control of standards, and the overall calibrations and quantification process. The findings in this area complement the findings of similar studies conducted by the Great Lakes Water Quality Board of the International Joint Commission.

The data quality management effort required intensivė record keeping and imposed a significant additional sample load on the participating project managers and supporting analytical laboratories. The effort necessary to staff and organize the process precluded using the review as a preventative measure in most cases. However, it did flag facilities having quality assurance problems, precluded the use of data outside the specifications demanded by specific studies and allowed participating laboratories to make corrections to their standards and procedure during the course of the study. The data quality effort ensured better data for decision making both for this study and for subsequent environmental activities. It demonstrated clearly that joint studies require more than a sharing of equipment, personnel and laboratory space but also an active, ongoing data quality management program between the United States and Canada. There is insufficient time during the design and planning phase of large multi-agency co-operative studies to develop a common data management program that will assure a reliable and compar- able data base during the subsequent study. Agencies must recognize the importance of quality assurance documentation as an on-going requirement, not only for internal laboratory reviews but also for external scrutiny.

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