Organohalogen Compounds, Volume 60, Pages 162-164 (2003)

QA/QC GUIDELINES FOR DIOXINS MEASUREMENT IN JAPAN

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Introduction

Dioxins analysis is rapidly increasing in number in Japan, reaching approximately 100,000 samples annually due to (a) growing public concerns over dioxin issue, and (b) enforcement of the Dioxins Control Law in January 2000. The law requires that prefectural governors must monitor environmental levels of dioxins in air, water and soil, and that owner of dioxins emitting facility under legal control must analyze dioxins levels in its flue gas, effluent water and fly ash at least once a year.

In an event of dioxins pollution, the quality of analyzed data attracts public attentions, leading sometimes to controversy in the local community. In particular the vegetable contamination case in Tokorozawa city in 1999, which news media including TV nationally broadcast, caused a nation-wide concern over dioxins including the reliability of data.

Under these circumstances, newly formed Ministerial Meeting against Dioxins decided in February 1999 the Basic Guideline for the Promotion of Measures. In addition to comprehensive measures to reduce dioxins emission, this guideline stresses the importance of QA/QC for dioxins analysis and urged relevant government agencies to take an action. Accordingly, Ministry of the Environment (then Environment Agency) established the Guidelines on Quality Assurance/Quality Control for the Environmental Measurements of Dioxins (Internal QA/QC Guideline) in November 2000 in order for dioxins laboratories to take measures to ensure the quality of its analysis. The ministry also set up the External QA/QC guideline in March 2001 covering measures taken by those who entrust dioxins analysis to the laboratories.

Internal QA/QC Guidelines

The Internal QA/QC Guideline sets forth measures to be voluntarily taken by laboratories responsible for environmental measurement of dioxins for the realization of appropriate quality control in such measurement activities.

Quality Control System:

A laboratory that performs environmental measurement of dioxins shall appoint a general supervisor, a quality controller, a technical manager and a measurement technician to ensure the proper management of its quality control system.

The general supervisor shall assume responsibility for entire operation of environmental measurement of dioxins. He appoints a quality controller, a technical manager and a measurement technician, as well as prepares a document on organization containing the names of persons he has appointed, tasks to which they are assigned and their experience in performing his work. The quality controller shall assume responsibility for quality control in environment measurement of dioxins. He examines (a) the draft of standard operating procedures, (b) the draft of a plan for quality control, and (c) the draft of a report on the results of quality control, and then submits these draft to the

general supervisor, and conduct internal audits. The technical manager shall assume responsibility for technical management of environmental measurement of dioxins, give technical instructions concerning the performance of tasks by the measurement technician, and check and retain the contents of records submitted by the measurement technician. The measurement technician shall prepare and keep records, and submit them to the technical manager.

The technical manager shall prepare the draft of document containing the procedures for checking records submitted by the measurement technician and procedures for dealing with problems that shall be required in case where the technical manager recognizes any quality control problems while checking the records.

The quality controller shall conduct an internal audit to ensure that quality assurance and quality control for environmental measurement of dioxins are properly implemented. He must prepare an internal audit report and submit it to the general supervisor. The audit shall be conducted once a year and more.

In case where the general supervisor deems it necessary for the quality controller, the technical manager and the measurement technician to perform their duties, he shall provide training for them (including training provided by external organizations and participation in technical proficient tests and inter comparison tests).

The general supervisor shall prepare a document specifying for drawing up the documents prescribed by these Guidelines and the procedure for maintaining and controlling these documents, and give instructions to the quality controller, the technical manager and measurement technicians so that these documents/records can be properly prepared, maintained and controlled in accordance with the procedure.

QA/QC Plan:

The technical manager shall make the draft of a QA/QC plan in connection with a series of operations for measurement of dioxins that his laboratory performs for the clients. The quality controller shall, if necessary, modify this draft plan and submit to the general supervisor. The general supervisor shall then examine it, give instructions to make modifications as required, and approve it.

The technical manager shall draw up the draft of a report on the results of QA/QC in connection with operations for measurement of dioxins performed in accordance with the QA/QC plan, and submit it to the quality controller. The quality controller shall examine this draft. If it has any quality control problem, the quality controller shall consult with the technical manager on measures to be taken in accordance with the procedures for dealing with QC problems. The general supervisor shall then examine it, give instructions to make modifications as required, and approve it. In case where modifications have been made to the original draft, the quality controller shall record the process leading to such modifications.

Individual QA/QC Requirements:

The measurement technician shall make and keep in records on reagents, standard solution, instrument, apparatuses, and facilities; and submit them to the technical manager. The technical manager shall check them.

The role and responsibility of each person are clarified in each process of dioxin measurement including collection of samples, pre-treatment of samples, measurement by GC/MS, finalization of results of quantitative determination, and reporting of results.

Results and Discussion

As an effort to make this guideline work and thus improve the quality of dioxins analysis among laboratories, Ministry of the Environment introduced in 2001 the pre-qualification examination on QA/QC in a process of awarding a contract to a private dioxins laboratory. Accordingly, only the laboratory that passed the pre-qualification examination is allowed to join the bidding for ministry-commissioned works with dioxins measurement. Accepting the application from private laboratory, the ministry examines in detail whether each laboratory follows the Internal QA/QC Guideline, seeking advice from a group of prominent scientists in dioxins analysis, and decides the applicant qualified or not. The qualified laboratories are publicly announced for the reference of other organizations that would award a dioxins-measurement contract. The table below shows the result of this examination in 2001 and 2002. Beyond expectations, most of the private dioxins laboratories in Japan applied for the pre-qualification examination even though Ministry of the Environment can provide a rather limited works for dioxins measurement. With a number of local governments making use of he result of this pre-qualification in selecting a private dioxins laboratory, the Internal QA/QC Guideline gained more power, and as a result QA/QC in a private laboratory is believed to be getting better.

The Result of Pre-qualification Examination

Year	Laboratory	No. of Application	No. of Passed	%
2001	Sampling and Analysis	91	60	66
	Sampling Only	64	11	17
	Total	155	71	46
2002	Sampling and Analysis	96	40	42
	Sampling Only	45	6	13
	Total	141	46	33

References

1. Ministry of Environment “Guidelines on Quality Assurance/Quality Control for the Environmental Measurements of Dioxins” (November 2000)
2. Ministry of Environment “Guideline on Securing the Reliability of the Environmental Measurements of Dioxins Commissioned Outside” (March 2001)

About MLAP

Specified Measurement Laboratory Accreditation Program (MLAP) is an accreditation system that was newly introduced with the amendment of Measurement Law of Japan in June, 2001 in order to enhance the reliability of certified measurement data of micro existent substances such as dioxins.

By the introduction of MLAP, a laboratory doing business for certifying measurement data of dioxins, etc. can apply for MLAP accreditation to National Institute of Evaluation and Technology (Note 1) and be accredited as an "accredited specified measurement Laboratory "(the effective date is April 1, 2002.).