

Guidelines on Securing the Reliability of the Environmental Measurements of Dioxins Commissioned Outside

These guidelines set forth measures to be taken by those consigning environmental measurements of dioxins to external organizations in Japan or foreign institutions.

1. Prior assessment of external organizations in Japan or foreign institutions

A consignor shall, in advance of consigning the environment measurements of dioxins (including open competitive contracts), pre-examine "external organizations in Japan or foreign institutions" (to be referred to as "external organizations") with the following points.

(1) Possibility of future consignees to carry out environmental measurements of dioxins

Concerning the environmental measurements of dioxins, a consignor is to investigate the terms of which the external organizations are capable of measuring, the consignees' operation areas, their measuring methods, their overall system performances, their past results, etc.

In order to do this, a consignor shall acquire the following materials:

- 1) Operation Area Matrix (note 1)
- 2) The "document on the organization" (note 2) described in Chapter 1-1-(1) of the "Guidelines on Quality Assurance/Quality Control for the Environmental Measurements of Dioxins" (announced on November 14, 2000 by the Environment Agency, to be referred to as "the Guidelines")
- 3) Achievement records (note 3)
- 4) Documents that specify that the consignees will or will not re-consign operations such as sample collection or measurements using the gas chromatograph mass spectrometer (note 4) (including joint orders. To be referred to as "re-consignment").

Based on the documents listed above (note 5), the consignor is to hold the first examination of future consignees on the possibility of their carrying out the environmental measurements (note 6).

- (Notes) 1. See appendix 1. When there are any restrictions of items, methods, or areas concerning the environmental measurements to be consigned, a consignor is to present such conditions to the consignees and acquire documents in return, in which the consignor can grasp the capability of the consignees.

2. See appendix 2. A consignor is encouraged to add/delete sections where necessary.
3. Operation results on each item (for the past three years by approximation). Where there are no or few results, a consignor shall request that they submit the document describing the reason why and the detail of actions that they have taken to make up for the shortage.
4. If the consignees WILL re-consign, a consignor shall request that they hand in the document describing its reason, specific name of the operations, name of the re-consignees, whether or not the re-consignees will/will not re-re-consign, method of overall operation management, where the responsibility resides, etc.
5. All documents shall include the preparation date. Foreign institutions can prepare all documents in English (this applies to all the documents mentioned hereinafter).
6. Upon request of external organizations, a consignor shall return to them the documents acquired after the first examination.

(2) Quality control and assurance

A Consignor shall, with regard to the external organizations that qualified the first examination (1) conduct investigations on their quality control and assurance status concerning the environmental measurements of dioxins (to be referred to as "internal quality control and assurance").

Firstly, in order to make sure that the terms regulated in the Guidelines are respected in the target external organizations, a consignor shall hand over the plan of operation contents to be consigned (be as detailed as possible), then request that its consignees submit the relevant documents (note 7-9). Furthermore, if possible, a consignor is encouraged to visit and carry out on-site investigations of the external organizations.

Based on the above, a consignor shall perform the second examination (note 10) to decide to which organizations the operation should be consigned (note 11-13). In cases when the qualified organizations may re-consign some of the operations (see the first examination), the consignor shall examine the re-consignees as well by completing the same procedures.

- (Notes) 7. See examination materials in Appendix 3. A consignor is encouraged to add/delete sections where necessary. The "relevant documents" should not strictly follow the exact form specified in the provisions set forth in the Guidelines; however, they are to be prepared based on the aforementioned provisions. Consignees shall also prepare documents for the terms that are not listed in the Appendix of the Guidelines; and likewise, those shall be in conformity with the aforementioned provisions.

8. A consignor shall remind its consignees that each document should bear the preparation date. If a certain document includes the past results of any particular measurements, the data of each must also bear its date of measurement.

9. A consignor shall request, in principle, such documents in written form. In the letter, a consignor shall clearly state and execute 1) that all materials received from consignees are used only for the purpose of examination and will not be provided to external organizations without the consignees' permission, 2) upon the request of consignees, that the consignor will return the documents to the consignees as soon as the examination terminates or when the documents are no longer of use.

10. Examination items are listed in Appendix 3. A consignor is encouraged to add/delete sections where necessary.

11. In cases of open competitive contracts (or the associated contracts), a consignor shall select two or more candidates in the second examination to make a final decision among them through competitive bidding, etc.

12. A consignor can simultaneously carry out the above-mentioned two examinations.

13. A highly technical and specialized knowledge is required for the second examination. Therefore, upon examination, a consignor can seek the cooperation of external experts and/or review similar examination results on the external organizations in question, which were carried out by third parties/organizations with reliability and transparency.

2. Requirements for external organizations upon consigning

Once the consignment contract with an external organization is settled after the second examination, a consignor shall confirm its consignees with the following requirements on quality control and assurance. In cases when the organization may re-consign a part of its operation, the consignor shall make sure that the re-consignees receive these requirements.

(1) Internal quality control and assurance

External organizations shall, on their operation plans, specify that they will perform internal quality control and assurance procedures in accordance with the provisions in the Guidelines and other relevant regulations.

(2) Submission of quality control and assurance plans

A consignee shall submit the quality control and assurance plans specified in Chapter 1-3-1 of the Guidelines or other relevant documents.

(3) Inspection

A consignor shall, during the period of consignment, conduct on-site inspections of consignees' institutions more than one time (note 14-17). All outside institutions

shall accept the inspections. Should a consignor fail to conduct the on-site inspections for particular reasons, the consignor can alternatively present the inspection items (note 18) to consignees, receive relevant materials from them, and make additional inquiries where necessary (note 19).

(Notes) 14. The on-site inspection items and documents that are to be collected upon each inspection are listed in the Appendix 4. A consignor is encouraged to add/delete sections where necessary.

15. In cases when a consignor has failed to conduct the on-site inspections at the point described in 1-(2), the consignor shall carry out the procedure immediately after the contract has been settled. When a consignor does carry out the inspections, but has consigned the measurement of considerable numbers of samples, the consignor shall, in principle, conduct further inspection when its consignee has finished measuring, using the gas chromatograph mass spectrometer, one third of the total samples.

16. A consignor shall send the advance notification of on-site inspections to its consignees in written form. In the letter, the consignor shall specify 1) the date, and 2) that all information acquired by inspectors or through inspections are used only for the purpose of quality control and assurance and will not be provided to external organizations without the consignees' permission.

17. A highly technical and specialized knowledge is essential for a proper on-site inspection. Therefore, the consignor is allowed to be accompanied by external experts or employ outside expert or/and organizations to carry out the inspection for them.

18. See Appendix 4. A consignor is encouraged to add/delete sections where necessary. In particular, as for the Standard Operating Procedures in C-1-3, the consignor shall take into consideration the enormous volume of the document. In line, upon requesting that consignees submit documents, a consignor is advised to take certain measures as described in Note 1 of Appendix 3.

19. When a consignor is certain from the start that they are unable to conduct on-site inspections, the consignor shall, in principle, conduct an alternative form of inspection when its consignee has finished measuring, using the gas chromatograph mass spectrometer, one third of the total samples.

(4) Quality assurance and quality control reports

Consignees shall, in addition to result reports, submit the Report on the Results of Quality Assurance and Quality Control or its relevant reports described in Chapter 1-3-2 of the Guidelines (note 20).

In addition, if necessary, in order to verify the calculation process, consignees shall submit and explain the record or relevant data specified in the Guidelines.

(Note) 20. If necessary, a consignor shall request that their consignees hand in 7. Attached Documents in the Attachment 2 of the Guidelines (Report on the results of quality assurance and quality control).

(5) Remeasuring

A consignor shall, when there are manifest faults in terms of external organizations, decide to re-measure consigned operations after consultation with the said organizations. On the event, external organizations in question shall specify information including the status of sample storage, etc. on their operation plans.

3. Others

A consignor shall, in addition to the above-mentioned process, take the following measures upon entrusting its operations to external organizations.

(1) Sample collecting session

With respect to the importance of quality control and assurance in sample collecting, it is recommended that a consignor observes the sample collection procedures of external organizations if possible, to make sure that the procedure is appropriately carried out.

(2) Cross checks

A consignor shall carry out cross checks when necessary, and make sure that the external organizations properly execute environmental measurements.

(3) Inspection records

A consignor shall record its inspection results after each on-site inspection described in 2-(3) of this document. In case any inappropriate operations are observed during the inspection, a consignor should discuss corrective actions with the external organizations concerned and ask them to take necessary measures.

(4) Examination of result reports

A consignor shall examine the reports submitted in accordance with arrangement 2-(4) of this document, and take the necessary measures (such as asking for further explanation) when there are any flaws detected in the document.

(5) Archiving of relevant materials

- 5) A consignor shall store, for the period of 5 years in principle, all documents acquired from external organizations (excluding those described in 1-(2) of this document, for they are to be returned after each investigation.), investigation reports (3), and reports on quality control and assurance (4).

Appendix 1 Operation Area Matrix

Items	Operation area				Measuring methods available	Notes
	Sample collection	Extraction from samples	Clean-up	GC-MS measurement		
Ambient air						
Dust fall						
Public water quality						
Ground water quality						
Soil						
Bottom sediment						
Wild life						
Aquatic life						
Emission gas						
Wastewater						
Dust						
Incineration ash & cinders						
Blood						
Food samples						

- (Notes) 1. Consignees are to put circles () in the boxes to show the items and operations that are available, and specify the possible measuring methods (e.g. JIL K 0311). Put a triangle () in the box if a certain operation is to be re-consigned (see note 4 of this document). In this case, consignees must give basic information of re-consignment under "notes".
2. Items can be added, corrected, or deleted where necessary. Note that "aquatic life" was separated from "wild life" for the sake of convenience.

Appendix 2 Materials concerning organization status

Items	(Material No.) Documents
1. Status of organizations	(A-1-1) Documents on the status of organizations (see Chapter 1-1-1 of the Guidelines) (note1)
2. Status of facilities	(A-1-2) Organization chart (note1) (A-2-1) Documents on the status of facilities (A-2-2) Documents on the operating conditions of facilities (see Chapter 2-1-5 of the Guidelines) (note 1)
3. Status of equipment and tools	(A-3-1) Documents on the overall condition and management status of equipment and tools (note 2)
4. Safety control	(A-4-1) Documents on the summary of safety control activities (note 3)

(Notes) 1. The documents do not need to strictly follow the exact form specified in the provisions set forth in the Guidelines; however, they are to be prepared based on the aforementioned provisions.

2. Including information on anti-pollution measures taken for highly concentrated samples.

3. Activities include safety management for workers and environmental pollution controls.

Appendix 3 Examination items and materials

Items	(Material No.) Examination materials
1. Quality control and assurance systems Procedures to deal with any operations improperly performed	(B-1-1) Documents on the summary of procedures to deal with operations improperly performed, prepared in accordance with the "procedures for dealing with QC problems" (see Chapter 1-1-2 of the Guidelines)
Internal audit	(B-1-2) The most recent "Internal audit report" (see Chapter 1-1-3 of the Guidelines) (Provide additional materials, if any, to describe additional procedures taken after the audit.)
Training, etc.	(B-1-3) Documents on the summary of training activities, etc. prepared in accordance with the "training report" (see Chapter 1-1-4 of the Guidelines).
Document control	(B-1-4) Documents on the summary of document control activities prepared in accordance with the "procedure for preparing, maintaining and controlling documents/records" (see Chapter 1-1-5 of the Guidelines) (also including descriptions on the treatment of data and documents stored onto electronic storage media).
Standard operating procedures	(B-1-5) The list of "standard operating procedures" (see Chapter 1-2-1 of the Guidelines) or the index of

<p>Task progress management</p> <p>Quality control and assurance measures taken by quality controller</p> <p>2. Reagents Management status of reagents and standard substance (solution)</p> <p>3. Collection of samples Sampling plan</p> <p>Particular points regarding sampling</p> <p>4. Pretreatment of samples Acceptance inspection, storage, and management of samples Sample pretreatment plan</p> <p>Particular points regarding sample pretreatment</p> <p>5. Measurement by GC-MS Inspection and adjustment of GC-MS</p> <p>Plan for measuring samples by GC-MS</p> <p>Calibration curve</p> <p>Lower limit of detection and lower limit of determination for apparatus</p> <p>Lower limit of detection</p>	<p>items (note 1)</p> <p>(B-1-6) Documents describing the summary of methods for task progress management</p> <p>(B-1-7) Documents describing the summary of quality control and assurance measures taken by quality controller</p> <p>(B-2-1) Documents describing the summary of management status of reagents and standard substance (solution)</p> <p>(B-3-1) Documents describing the summary of sample collection plans (of operations to be consigned)</p> <p>(B-3-2) Documents describing the summary of particular points in terms of quality control and assurance concerning sample collecting operations (to be consigned)</p> <p>(B-4-1) Documents describing the summary of acceptance inspection, storage, and management of samples (of operations to be consigned)</p> <p>(B-4-2) Documents describing the summary of sample pretreatment plans (of operations to be consigned)</p> <p>(B-4-3) Documents describing the summary of particular points in terms of quality control and assurance concerning sample pretreatment (of operations to be consigned)</p> <p>(B-5-1) The "implementation standard for inspection of GC-MS" (see Chapter 2-4-2 of the Guidelines)</p> <p>(B-5-2) Documents describing the current operation status of the inspection and adjustment of GC-MS</p> <p>(B-5-3) Documents describing the summary of plans for measuring samples by GC-MS (of operations to be consigned) (including plans for field blank test, travel blank test, dual measurement, and measurement of sample of known concentration. See Section 3 to 6 of Chapter 2-5 of the Guidelines)</p> <p>(B-5-4) The calibration curve and its chromatogram (see Chapter 2-4-4 of the Guidelines) (those for which one can check the identification and signal strength of each peak, including that of internal standard substance)</p>
---	--

<p>and lower limit of determination for the measuring method Field blank test, travel blank test, and dual measurement</p>	<p>(B-5-5) Documents that specify the lower limit of detection, lower limit of determination for apparatus, and their calculation processes (see Chapter 2-5-1-(1) of the Guidelines) (note 4)</p> <p>(B-5-6) Documents that specify the lower limit of detection and lower limit of determination for the measuring method, and their calculation processes (see Chapter 2-5-1-(2) of the Guidelines) (note 3)</p>
<p>Chromatogram of internal standard substance</p>	<p>(B-5-7) Documents describing the summary of the results of field blank test, travel blank test, dual measurement, and measurement of sample of known concentration (See Sections 3 to 5 of Chapter 2-5 of the Guidelines) (note 3)</p>
<p>Separation of each isomer</p>	<p>(B-5-8) The chromatogram of internal standard substances in the sampling spike, cleanup spike, and syringe spike (those that one can check the signal strength of each peak) (note 3)</p>
<p>6. Participation or accomplishments in inter-laboratory comparison testing of dioxins</p>	<p>(B-5-9) The chromatogram that shows the identifications of all isomers, and by which one can check the separations of chlorinated isomers in the levels of 2,3,7 and 8 (provide enlarged pictures where necessary).</p>
<p>7. Other quality control and assurance activities</p>	<p>(B-6-1) Documents concerning the participation or accomplishments in the inter-laboratory comparison testing of dioxins (5)</p> <p>(B-6-2) Documents describing other quality control and assurance activities</p>

- (Notes) 1. After examining each material, a consignor may, if necessary, request that its consignees submit the "Standard Operation Procedures" of the relevant operation. Note, however, that these documents can be considered as the bottom line of each organization's technology, that some information may not be available for disclosure. Based on this understanding, a consignor shall request such documents in a written form and specify: 1) the Standard Operation Procedures received from consignees will be returned as soon as the examination ends, and 2) the consignor will not make any copies of original documents received.
2. The information shall include the means of transportation after the collection of samples.
3. Materials shall be prepared based on the most recent measurement results of the same object items as those to be consigned.
4. Materials shall be prepared based on the most recent measurement results of those conducted for the calculation of the lower limit of detection for an apparatus.
5. If there were no notable accomplishments from the inter-laboratory sessions, consignees shall hand in the document describing the possible factors and provide information on any actions they may have taken to improve the situation.

Appendix 4 On-site inspection items and documents to be collected upon inspection

Inspection items	(Material No.) Documents to be collected upon inspection
<p>1. Quality control and assurance (status) Internal audit (status) Training, etc. (status) Standard operating procedures</p> <p>2. Facilities and reagents (status) Management status of facilities Management status of reagents and standard substance (solution)</p> <p>3. Operating systems (of operations consigned) Operating system (of operations consigned) Task progress and methods for task progress management (of operations consigned) Quality control and assurance measures taken by quality controller, and future plans</p> <p>4. Collection of samples (of operations consigned) Management status of equipment and tools Status of sample collection Inappropriate operations observed</p> <p>5. Pretreatment of samples (of operations</p>	<p>(C-1-1) Internal audit reports which are conducted after the preparation of (B-1-2) of examination materials, Appendix 3 (C-1-2) Revised version of (B-1-3) of the examination materials, Appendix 3 (if available) (C-1-3) Standard operating procedures corresponding to (B-1-5) of the examination materials, Appendix 3</p> <p>(C-2-1) Documents that describe the summary of the management status of facilities (C-2-2) Revised version of (B-2-1) of the examination materials, Appendix 3 (if available)</p> <p>(C-3-1) Documents describing the operating system (of operations consigned) (C-3-2) Documents describing the summary of the task's progress and methods for task progress management (of operations consigned) (C-3-3) Documents describing the summary of quality control and assurance measures taken by quality controller, and future plans</p> <p>(C-4-1) Documents describing the status summary of the management of equipment and tools (C-4-2) Documents describing the status summary of the sample collection status prepared based on the records specified in Chapter 2-3 of Part 2 of the Guidelines (C-4-3) Documents describing the status of any corrective actions taken against inappropriate operations (if any)</p> <p>(C-5-1) Documents describing the status summary of the management of equipment and tools (C-5-2) Documents describing the status summary of</p>

<p>consigned) Management status of equipment and tools Status of acceptance inspection of samples Status of storage and management of samples</p> <p>Status of sample pretreatment</p> <p>Inappropriate operations observed</p>	<p>the acceptance inspection of samples, prepared based on the records specified in Chapter 3-2-(1) of Part 2 of the Guidelines</p> <p>(C-5-3) Documents describing the status summary of the storage and management of samples, prepared based on the records specified in Chapter 3-2-(2) of Part 2 of the Guidelines</p> <p>(C-5-4) Documents describing the status summary of the sample pretreatment, prepared based on the records specified in Chapter 3-2-(3) of Part 2 of the Guidelines</p> <p>(C-5-4) Documents describing the status of any corrective actions taken against inappropriate operations (if any)</p>
<p>6. Measurement by GC-MS (of operations consigned)</p> <p>Operation status</p> <p>Inappropriate operations observed</p>	<p>(C-6-1) The "injection list" specified in Chapter 4-5 of Part 2 of the guidelines (with sample name, date and time)</p> <p>(C-6-2) Documents prepared for checking resolution, prepared based on the record specified in Chapter 4-3-(2) of Part 2 of the Guidelines</p> <p>(C-6-3) Documents prepared for checking peak separation and absolute sensitivity, prepared based on the record specified in Chapter 4-3-(3) of Part 2 of the Guidelines</p> <p>(C-6-4) The calibration curve created as a result of the procedure specified in Chapter 4-4 of Part 2 of the Guidelines</p> <p>(C-6-5) Documents prepared for the checking of the variation of sensitivity, prepared based on the record specified in Chapter 4-6 of Part 2 of the Guidelines</p> <p>(C-6-6) Documents prepared for the checking of lock mass channel variation, prepared based on the record specified in Chapter 4-7 of Part 2 of the Guidelines</p> <p>(C-6-7) Documents prepared for the checking of cleanup spike recovery and sampling spike recovery, prepared based on the record specified in Chapter 5-2 of Part 2 of the Guidelines</p> <p>(C-6-8) The measurement results of field blank test, travel blank test, dual measurement, and measurement of sample of known concentration prepared based on the records specified in the sections 3 to 6 of Chapter 5 ,Part 2 of the Guidelines</p> <p>(C-6-9) Documents describing the status of any corrective actions taken against inappropriate operations (if any)</p>
<p>7. Quality control and assurance activities carried out for re-consignees</p>	<p>(C-7-1) Documents describing the activities summary of quality control and assurance, carried out for</p>

	re-consignees
--	---------------

(Note) In cases when there has been no operation carried out at the moment of on-site inspection (since a consignor made the inspection right after the settlement of contract- see note 15 of this document), consignees shall submit all possible materials prepared based on the past operation results of the same object items