

Green Procurement Assessment Chemicals Control Manual Ver.1.1

1. Objective

The objective of this manual is to describe a control system that we require each vendor to operate, and expect each supplier to be highly conscious of environmental activities, for conducting green procurement assessment.

2. Assessment Strategy

Each vendor should conduct self-assessment using the "Green Procurement Assessment Form" and submit a completed Form to our procurement department.

Status of "Environment Management System Establishment" and "Process Control/Environmental Quality Assurance" on chemicals needs to be assessed.

3. Control of Chemicals Contained in Products

Environment Management System Establishment

1. Policy

Category	Assessment Items	Answer (Choose from the drop-down list)
1. Policy	1 Do you have policies on the environment?	None. Under creation or not approved yet. Policies exist, but are not documented. Documented, approved policies exist, and are communicated only to parties concerned. Documented, approved policies exist, and are communicated to all the employees.
	2 Does the policy state any activities relating to chemicals contained in your products?	Not specified. Policy Specifies no control of chemicals contained in products, but describes chemicals. Control of chemicals contained in the products is specified by documents separated from the policies. Policy Specifies activities for control of chemicals contained in the products. Policy Specifies control of chemicals contained in the products, including activities for conformity with relevant regulations.

The environmental policy should be announced by the management of the business to define the intent and orientation of environmental activities and provide a framework for all the environmental activities.

The environmental policy should refer to activities involving hazardous chemicals through documentation by the management of the business. A mechanism that enables the activities to be understood by all the employees should be provided and the activities should be thoroughly communicated to all the employees.

* Strategy for addressing chemicals should be provided.

- Activities for compliance with regulations and control of chemicals contained in products should be referred to.
- The environmental policy should specify that requirements of relevant regulations should be fulfilled.
- Activities for control of hazardous chemicals should be referred to.

* The environmental policy should be approved by the management of the business and understood by all the employees.

Critical Points

- 1) Company's agreements or commitments on the use of hazardous chemicals should be referred to.
- 2) The policy document should carry the signature or seal of the management of the business.
- 3) The policy should be appropriately reviewed considering social demands and customers' requirements on a regular basis.
- 4) The policy should be communicated to all the employees.

2. Defining Control Criteria

Category	Assessment Items	Answer (Choose from the drop-down list)
2. Defining Control Criteria	3 Do you control information on chemicals contained in your products?	Not controlled. Although no approved rule exists, information on customer requirements is controlled. Approved rules exist, and information on customer requirements is controlled. Approved rules exist, and information on customer requirements, regulations, and industry standards is controlled. Approved rules exist, and information on customer requirements, regulations, and industry standards is controlled and reflected in internal standards.
	4 Do you have any rules to comply with our Green Procurement Guideline referring to chemicals contained in your products?	The Green Procurement Guideline is not preserved or controlled. Although approved rules for compliance exist, they are not reflected in internal standards. Although no rule for compliance exists, internal standards are harmonized with it. Approved rules for compliance exist and are reflected in internal standards. Approved rules for compliance exist and are reflected in internal standards; relevant departments surely follow them.

Information on regulations, industry standards, and customers' requirements relating to chemicals contained in products should be controlled. The company's own control criteria should be defined and communicated to relevant departments.

- * Documents relating to regulations, industry standards, and customers' requirements on chemicals contained in products should be properly arranged and controlled.
- * The company's own control criteria for regulations and chemicals should be defined.
- * The company's own control criteria should be communicated to relevant departments and subsidiary companies including subcontractors.

Critical Points

- 1) Documents on relevant regulations and customers' requirements should be controlled and always maintained up date.
- 2) The Green Procurement Guideline issued by us should be preserved and controlled.
- 3) The company's own control criteria should be harmonized with regulations, industry standards, customers' requirements, and our Green Procurement Guideline.
- 4) Paths for communicating information on relevant regulations, customers' requirements, and the company's own criteria should be defined. Necessary directives and notifications should be thoroughly communicated using documents to all the departments.

3. Defining Scope of Control/Organizations

Category	Assessment Items	Answer (Choose from the drop-down list)
3. Defining Scope of Control/Organizations	5 Do you define "organizations/tasks/processes," "chemicals," "components," and "products" , so that control of chemicals contained in your products should cover?	No documented scope. A documented scope for organizations, tasks, processes, and products exists. A documented scope that also covers elements, referring to the left, including sub(indirect) materials, as well as the above exists. A documented scope that also covers subcontractors, if any, as well as the above exists. A documented scope that covers all of the above exists and is communicated to relevant departments.
	6 Do you have organizations, roles, responsibilities, and authorities defined for control of chemicals contained in your products?	No organization is defined. Although organizations exist, no role, responsibilities, or authorities are defined. Each task performer understands its role, responsibility, and authority, though they are not documented. Although documented organizations, roles, and authorities exist, improvement in their communication is necessary. Documented organizations, roles, and authorities exist along with defined responsible persons, and are communicated.

The scope of control of chemicals contained in your products should be defined. "Organizations/tasks/processes," "chemicals," "components," and "products" should be defined in the scope of control.

Control criteria for chemicals should be specified and the roles, responsibilities and authorities on chemicals should be defined in each department.

* Organizations and departments for promoting control of chemicals should be defined and control of chemicals should be organizationally implemented.

Example: The Chemicals Control Lead monitors hazardous chemicals, suspends or releases shipment upon abnormality, and directs cause analysis and recurrence prevention.

* Tasks, chemicals, elements, processes, and/or products that each department covers should be defined.

Example 1: The sales department collects and communicates information on regulations and the customers' requirements and traces shipped products.

Example 2: The material department controls information on the suppliers, controls categorized materials, and copes with failed materials.

Example 3: The design department defines target chemicals and products in the design specifications, collects data on the materials and chemicals of new elements, and conducts change control.

Example 4: The manufacturing department controls the non-use of hazardous chemicals, controls the manufacturing processes and facilities, and controls each production lot.

Example 5: The quality assurance department inspects incoming materials to determine their acceptance, inspects target products and determine their shipment, and approves and controls data on chemicals.

* The organizations specified in the "Defining Scope of Control" should identify information required for control of chemicals contained in the products, and appropriately communicate and share the information.

Critical Points

- 1) The organization that promotes company-wide activities to control hazardous chemicals should exist.
- 2) The management of the business should administer the organizations.
- 3) The assignment of roles and responsibilities among each department should be defined.
 - The "Organization" may include the material department, design department, manufacturing department, and quality assurance department.
 - The "Task" may include the incoming inspection and shipment inspection.
 - The "Element" refers to materials, components, and sub(indirect) materials that form a product.
 - The "Process" may include the production processes and subcontractors.

4. Objectives/Plans

Category	Assessment Items	Answer (Choose from the drop-down list)
4. Objectives /Plans	7 Do you have objectives and plans established for control of chemicals contained in your products, considering regulations and customer requirements?	Not created. Under creation or not approved yet. Although no approved objective/plan exists, regulations and customer requirements are considered. Although approved objectives/plans exist, no progress control or review is conducted. Approved objectives/plans exist, and progress control and review are conducted.

Objectives and plans for control of chemicals contained in your products should be established considering regulations and customer requirements.

- * Plans for reducing or abolishing hazardous chemicals, considering regulations and customers' requirements, should exist.
- * The objectives and plans should be reviewed as necessary in accordance with new regulations or the latest industry standards. The progress in achieving the objectives should be made obvious.

Critical Points

- 1) For activities for achieving the objectives and plans, the deadline, persons who should do, what should be done, and how it should be done should be defined. A person who is responsible for the activities should be also defined.
- 2) Whether the activities are being carried out in line with the plans should be timely verified. Record of the verification should be preserved.

5. Education/Training

Category	Assessment Items	Answer (Choose from the drop-down list)
5. Education/Training	8 Do you have rules established for education and training for control of chemicals contained in your products, and conduct necessary education and training?	No education/training is conducted. Although no approved rule exists, education/training is conducted as necessary, but no record is preserved. Although no approved rule exists, education/training is conducted as necessary and its record is preserved. Although approved rules exist and education/training is conducted, some improvement for its complete implementation, including content and attendance control, is necessary. Approved rules exist, education/training is conducted for appropriate employees according to plans, and the content and attendance are thoroughly controlled.

Rules of education that lets all the employees understand the environmental policy should exist. With appropriate trainees and necessary curriculums arranged and identified, education/training should be provided.

- * Latest information should be thoroughly communicated that makes knowledge and consciousness of regulations and hazardous chemicals to be richer and allows all the employees to understand their importance.
- * Specific education/training should be provided for persons who engage in tasks that may considerably affect environment.
- * All the persons who are assigned tasks the organization specifies should have necessary skills based on appropriate education, training, or experience they have had.
- * Education record of the trainees who participated in and curriculums should be preserved.

Curriculums of education/training

- (1) Details of trainees' tasks: Relation between control of chemicals and their tasks
- (2) Ideas of control of chemicals contained in products: Necessity of abolition of hazardous chemicals
- (3) Related regulations and industry standards: Identifying controlled substances, and latest information
- (4) Risk management of chemicals: The name of materials that generally contain banned substances
- (5) Uses, analysis methods, and failure scenarios of controlled substances: Locations or purposes where specific chemicals are commonly used, examples of failure caused by chemicals, and handling of XRF ICP analyzer.

Critical Points

- 1) Education/training on hazardous chemicals should be regularly scheduled and provided to all the employees.
- 2) It should be verified that the curriculums to be used for education/training are appropriate.
- 3) Record of the results from provided education/training should be verified.

6. Documentation

Category	Assessment Items	Answer (Choose from the drop-down list)
6. Documentation	9 Do you have documents, such as manuals, rules, standards, procedures, and documentation system charts, that enable you to understand your company-wide or office-wide rules or relevant information relating to control of chemicals contained in your products? Do you also preserve and control them?	No document exists that facilitates understanding overall rules and relevant documents. Although no document exists that facilitates understanding overall rules and relevant documents, individual rules and relevant documents exist. Documents exist that facilitate understanding overall rules and relevant documents, and overall rules can be understood. In addition to the above, documents are regularly reviewed. In addition to the above, rule and relevant documents can be available anytime at any department if they are required.
	10 Do you generate and preserve performance record of control of chemicals contained in your products? The record may include information on contained chemicals, acceptance/shipment verification data, internal audit record, and survey/analysis data.	No record is generated or preserved. Although approved rules exist, no record is generated or preserved. Although no approved rule exists, the record is generated and preserved. Approved rules exist and the record is generated and preserved, though some improvement for retrieval is necessary. Approved rules exist, the record is thoroughly generated and preserved, and it can be quickly retrieved.

Rules for creation, implementation, maintenance, and control of documents should be established in accordance with regulations and requirements related to chemicals contained in the products.

Record of results should be also appropriately generated and preserved.

* Rules should be provided that enables documents on relevant regulations and customers' requirements to be systematically controlled and always maintained up to date.

Critical Points

- 1) It is important to create a document or documentation chart that can systematically illustrate the company's system for control of chemicals contained in the products and related documents.
- 2) The document should be so reviewed as needed that its latest version can be referred anytime when it is required.
- 3) The document may include the policy, manual for control of chemicals contained in the products, related procedures for control of chemicals, rules, standards, criteria, instructions, and documentation chart.
- 4) Modified portions in documents and current revised versions should be surely identifiable.
- 5) The record may include information on chemicals contained in the products, acceptance verification data, shipment verification data, internal audit results, survey data, and analysis data.
- 6) Recorded contents should be so readable that the actual targets can be traced.

7. Report Obligation

Category	Assessment Items	Answer (Choose from the drop-down list)
7. Report Obligation	11 Can you report information on chemicals contained in your products according to our Green Procurement Guideline?	Cannot be reported. Can be reported, but not in line with the Green Procurement Guideline. Can be reported with the "JGPSSI Survey Response Tool" (the third priority) in accordance with the Green Procurement Guideline. Can be reported with the "Material Contents Report" (the second priority) in accordance with the Green Procurement Guideline. Can be reported with the "JAMP AIS" (the first priority) in accordance with the Green Procurement Guideline.

Contained chemicals information in the supply chain (OUT information) should be appropriately controlled and information on chemicals contained in the products should be able to be reported.

* A means or mechanism that provides information on chemicals contained in the products should be available.
For molded products (articles), the means may include the JAMP AIS, JGPSSI Survey Response Tool, and JAMA/JAPIA Standard Material Datasheet.
If products to be supplied are substances or preparations, the means may include the MSDS and MSDSplus.

Critical Points

- 1) Information on chemicals contained in the products should be available for reporting in accordance with our Green Procurement Guideline.
For reporting, use the JAMP AIS, which can carry all the contained chemicals information, as the first priority form, and the Material Contents Report as the second priority form. If neither of them can be used, the JGPSSI Survey Response Tool may be used as the third priority form. If, however, the JGPSSI Survey Response Tool (third priority) form is used, additional information may be required.
- 2) Chemicals surveys should have been conducted in accordance with our Green Procurement Guideline.
- 3) Information should be available for reporting immediately upon customer's request.
- 4) Necessary information exchange among the supply chain should be smoothly made.

8. Evaluation/Improvement of Implementation

Category	Assessment Items	Answer (Choose from the drop-down list)
8. Evaluation /Improvement of Implementation	12 Do you conduct internal audits to regularly verify the state of control of chemicals contained in your products, make necessary improvement if any, and report the verification results to your management?	No internal audit is conducted. Although approved rules exist, no internal audit is conducted. Although no approved rule exists, internal audits and improvement are conducted. Approved rules exist. Although internal audits and improvement are conducted, they are not reported to the management. Approved rules exist. Internal audits and improvement are conducted, and are reported to the management.

In order to determine whether the activities on the quality are carried out as decided or planned and whether the activity status are appropriate for the objectives, internal audits are conducted.

* Audits and associated follow-ups should be conducted under common understanding with documented procedures.

* Specific persons, such as those qualified for an ISO9000 internal auditor, should be designated as internal auditors who audit the status of hazardous substance control.

(1) Create procedures or rules for internal audits and, in accordance with them, conduct and record each audit.

(2) Conduct the audit using a check sheet.

(3) Ensure that improvements have been made against any previous findings and their effect is valid.

(4) Document the audit results to describe findings and allow follow-up of the findings to be developed.

(5) Document the ultimate audit results and report it to the management of the business, allowing the management review.

(6) Horizontally propagate the audit results to raise the overall level so that the same problems would never occur again.

* Internal audit for environmental quality assurance system

An internal mechanism should exist that enables internal audits on our banned substances to be regularly conducted.

Process control status and countermeasures against previous problems should be maintained.

Critical Points

1) The items to be checked during an internal audit should include our banned substances.

2) An internal audit should be conducted at least annually.

3) Internal audit results, with corrective actions applied to any failure in compliance, should be reported to the management of the business.

4) The management should receive the internal audit results and status of failure in compliance, and implement improvement by reflecting themes, if any, in the next term objectives.

Process Control/Environmental Quality Assurance

9. Development/Engineering Design Management

Category	Assessment Items	Answer (Choose from the drop-down list)
9. Development/ Design Management	1 Do you verify information on chemicals contained in each component/material, and design your products and manufacturing processes so that they would comply with the control criteria?	Designing not considering information on contained chemicals. Approved rules exist, but are not implemented. Although no approved rule exists, information on contained chemicals is confirmed. Approved rules are implemented, and some improvement in their provisions or communication is necessary. Approved rules exist, and information on chemicals are confirmed during design of products and processes.

Information on chemicals contained in each component/material should be verified for compliance with relevant requirements, the products and manufacturing processes should be designed so that they would comply with the control criteria, and the completed products should be verified for compliance with the control criteria.

* Chemicals contained in components, materials, and sub(indirect) materials that are used during the product design stage should be verified.

* Documents on relevant regulations and customers' requirements should be preserved and always maintained up to date.

* Control criteria for chemicals should exist to define chemicals and criteria subjected to the control.

Critical Points

1) When manufacturing products, information on chemicals contained in the materials should be confirmed.

2) It should be verified that sub(indirect) materials used in the manufacturing processes do not contain hazardous chemicals.

3) In a case where the concentration or properties of contained chemicals may vary in the manufacturing processes, the products should be verified for compliance with the control criteria by considering the variation.

4) The used amount of restricted substances should be made obvious. Whether it can be reduced should be validated, and the assessment for reduction should be conducted.

10. Purchase Management

Category	Assessment Items	Answer (Choose from the drop-down list)
10. Purchase Management	2 Do you obtain information on chemicals contained in components/materials you purchase, verify that they comply with relevant requirements, and control necessary documents?	No control criteria exist, no conformity is verified, and no control is implemented. Although conformity is verified, no document is controlled. Although no approved rule exists, conformity verification and document control are implemented. Approved rules exist, and conformity verification and document control are thoroughly implemented. Approved rules exist, conformity verification and document control are thoroughly implemented, and any necessary reports can be promptly provided.
	3 Do you verify that your vendors, including each vendor's vendors and vendors of each vendor's vendor, have established a chemicals control system and rules to eliminate banned chemicals?	Not verified. Approved rules exist, but no vendor is verified. Although no approved rules exist, vendors are verified. Although approved rules exist and vendors are verified, no vendor audit is conducted. Approved rules exist, vendors are verified, and audits are conducted as needed.

10-1. Obtaining and Confirming Information on Contained Chemicals

Information on chemicals contained in purchased materials (input information) should be obtained and it should be verified that the materials comply with the control criteria.

* Information on chemicals contained in purchased materials should be obtained. This information include identification of whether chemicals are contained or not, the content or concentration, and the purposes.

* It should be verified that the purchased materials comply with the control criteria and the contained chemicals information should be controlled.

Critical Points

- 1) For new or modified materials, the contained chemicals information complying with the control criteria should be obtained and confirmed before the mass-production starts.
- 2) Chemicals surveys should have been conducted in accordance with our Green Procurement Guideline.
- 3) The company's own control criteria should be harmonized with regulations, industry standards, customers' requirements, and our Green Procurement Guideline.

10-2. Verifying Control Status of Vendors

A mechanism should exist that can be used to determine whether a vendor has a chemicals control system and rules that prevent banned chemicals from being contained.

A mechanism should exist that can be used to request a vendor to implement control for compliance with your own criteria and regularly conduct vendor audits.

Critical Points

- 1) A purchase control rule should exist that includes assessment of vendors for their environmental load reduction activities, including abolition or reduction of hazardous chemicals.
- 2) When choosing a vendor, the vendor's control status should be assessed.
- 3) The supplier status of control of chemicals contained in their products should be verified.

11. Acceptance Verification

Category	Assessment Items	Answer (Choose from the drop-down list)
11. Acceptance Verification	4 Do you have rules established to verify, when products, materials, and components are delivered to you, that they contain no banned chemicals that our Green Procurement Guideline specifies?	No rule exists. Although no approved rule exists, acceptance is determined using information each vendor supplies. In accordance with approved rules, acceptance is determined and its record is preserved. In accordance with approved rules, acceptance is determined using information each vendor supplies for each lot. In accordance with approved rules, acceptance is determined by internally analyzing products with analyzers, such as an X-ray analyzer, depending on their risk level.

A mechanism should exist that enables delivered products, raw materials, and components to be inspected for hazardous chemicals when receiving them.

* Compliance with the requirements regarding the specific banned substances specified in our Green Procurement Guideline should be able to be verified.

* Specific procedures for acceptance inspection of raw materials, components, and products for hazardous chemicals should be established, with an objective that no environmental load chemicals are allowed to come inside the company.

Critical Points

- 1) Control criteria on the contents of hazardous chemicals should exist and be documented.
- 2) Acceptance inspection for products and components should be performed based on the control criteria. The inspection record should be generated and preserved.
- 3) Target hazardous chemicals, acceptance criteria, sampling quantities, and sampling frequencies should be defined.
- 4) Specific procedures for coping with abnormalities should be defined.
- 5) If analyzers, such as an XRF, are available, the measurements from them should be used to determine acceptance. Otherwise, analysis data attached, such as ICP data, should be used.
- 6) If an external body performs acceptance inspection or measurement, the body should be reasonably competent and reliable.

12. Process Control

Category	Assessment Items	Answer (Choose from the drop-down list)
12. Process Control	5 Do you have rules established to prevent misuse of, mixture of, and contamination by components/materials within your manufacturing processes? Means for the prevention may include part number control, separate storage locations, item number control, and cleaning tools.	No rule exists. Approved rules exist, but are not implemented. Although no approved rule exists, a preventive means is implemented. Approved rules are implemented, and some improvement in their provisions or communication is necessary. Approved rules exist and are implemented. Control record for key processes is preserved.

Measures should be taken that prevent chemicals to be controlled from being misused, being mixed, or contaminating others.

* Rules should exist that control misuse, mixture, and contamination involving banned substances during work in the manufacturing processes and in the production facilities.

* Means should be defined that can be used to verify no contamination by equipment, tools, or containers has occurred.

* Chemicals to be controlled should be so controlled that its variation in the composition or concentration would not cause the chemicals left or generated in a manner exceeding the control criteria.

Critical Points

- 1) The control process chart or process flow chart of the QC process chart should specify control items related to hazardous chemicals for each process.
- 2) Unfinished products should be separately controlled in the processes so that they would not be mixed between different lots.
- 3) Criteria for cleaning equipment, tools, and containers should be defined to prevent contamination.
- 4) It should be verified that recycled materials, if any, do not contain banned substances.
- 5) The used amount and presence of added materials, such as additives and pigments, should be controlled.
- 6) Any processes, where the composition of chemicals may vary due to oxidization, deoxidization, or reactions or the concentration of chemicals may vary due to vaporization or volatilization, should be identified and properly controlled.

13. Subcontractor Control

Category	Assessment Items	Answer (Choose from the drop-down list)
13. Subcontractor Control	6 Do you notify your subcontractors of necessary requirements for control of chemicals contained in the products?	Not applicable. We don't notify. Although approved rules exist, we don't notify them of the requirements. Although no approved rule exists, we notify them of the requirements. Approved rules exist and we notify them of the requirements, though no record exists. Approved rules exist and the record of notification is preserved.
	7 Do you verify each subcontractor's control system?	Not applicable. Not verified. Approved rules exist, but no subcontractor is verified. Although no approved rule exists, each subcontractor is verified and its record is preserved. Approved rule exist, each subcontractor's control system is verified with documents, and its record is preserved. Approved rule exist, each subcontractor's control system is verified through regular audits, and their record is preserved.

Requirements of necessary chemicals control should be communicated to subcontractors and their control system should be regularly evaluated.

The control level of a supplier that supplies their products to another supplier should be the same as the later supplier in principle.

* A mechanism should exist that enables you to require subcontractors to implement control with the same level as you and regularly conduct audits their control status.

* A mechanism should exist that enables you to determine whether your subcontractor, including its subcontractors and its subcontractor's subcontractors, has a chemicals control system and a mechanism that can prevent banned substances from being contained in the products the subcontractor provides you.

* Purchase management rules should exist and the assessment items should include items that assess supplier's environmental load reduction activities, such as abolition or reduction of hazardous chemicals. When choosing suppliers, that assessment should be conducted.

Critical Control Points

- 1) Acceptance inspection for raw materials should be performed and only accepted materials should be used.
- 2) The control department and persons in charge in each subcontractor should be defined.
- 3) Each subcontractor should enter into an agreement with you on control of hazardous chemicals.
- 4) Information on the threshold levels for hazardous chemicals should be provided to each subcontractor.
- 5) Along with a quality audit, an audit on control of hazardous chemicals should be conducted to verify the control status.
- 6) A mechanism should exist that prevents a subcontractor from using raw and sub(indirect) materials only at its discretion.

14. Verification on Shipment

Category	Assessment Items	Answer (Choose from the drop-down list)
14. Verification on Shipment	8 Do you have rules established to ultimately verify, when you deliver your products, that they contain and use no banned chemicals that our Green Procurement Guideline specifies?	No rule exists. Approved rules exist, but are not implemented. Although no approved rule exists, deliveries are verified and the record is preserved. In accordance with approved rules, deliveries are verified and the record is preserved. In addition to the above, deliveries are inspected with analyzers, such as an X-ray equipment, as necessary.

Rules should be so configured that details on chemicals control can be verified before shipment.

Specific banned substances criteria that comply with our Green Procurement Guideline should be fulfilled.

* Products should be shipped only after specified verification items, including those that should be verified on their acceptance and during their manufacturing, have been found to be fulfilled.

* The shipping inspection standard should include control criteria on hazardous chemicals and the inspection should assure that shipped products do not contain those chemicals.

* The shipping record should be controlled and traceability for shipped products should have been established.

Critical Control Points

- 1) Regularly analyzing shipping products or verifying the evidence, such as ICP data for raw materials and components, should assure the quality of shipped products.
- 2) The accuracy or detection limits of XRFs or ICPs should be sufficient if they are used for inspection.
- 3) When asking an external body for measurement for data, such as ICP data, the body should be reasonably reliable and competent. The analysis data document from the body should carry the seal of that body.
- 4) Results of analysis performed for each lot, regularly, and/or optionally for contained chemicals of shipping products should be recorded, documented, and preserved.
- 5) In each shipping warehouse and external distribution warehouse, completed products should be controlled so that wrong products would not be shipped or different products would not be mixed.
- 6) When failure in compliance has arisen, appropriate actions should be taken.

15. Traceability

Category	Assessment Items	Answer (Choose from the drop-down list)
15. Traceability	9 Do you have rules established to enable you to trace each production lot from the acceptance of materials, components, and products to the shipment?	No rule exists. Although approved rules exist, lots cannot be traced. Although no approved rule exists, each lot can be traced with its record. Approved rules exist and each lot can be traced with its record, but it needs some time. Approved rules exist and each lot can be quickly traced with its record.

Rules should exist that enable chemicals to be traced on a lot basis from the acceptance stage to the shipment stage of raw materials, components, and goods.

Rules should exist that prevent failure products or lots from being mixed with good ones and enable their identification.

* Record of the origins, manufacturers, delivery history, evidence, and process history of raw materials should be preserved. The record should be able to be traced to identify the region where failure in compliance has occurred and report the failure to the delivery destinations of the subject materials.

* The method of recording and preserving information, including change information, should be confirmed.

* It is important for each process to control information on control, abnormalities, and factor changes.

* It is important to identify or isolate products depending on each risk.

Critical Control Points (Practical examples)

1) Record of raw material use from its acceptance to its consumption in each process should be generated and preserved. The record may include information on chemicals, control, abnormalities, and factor changes.

2) Raw materials, components, and products that need to be traced should be given an identification unit and controlled with assigned identifiable symbols or numbers.

3) Raw materials, components, and products should be controlled separately for each identified unit.

4) Record should exist that correlates each acceptance lot of raw materials and components with a shipped product lot and its destination.

5) Even if a lot of raw materials has been split into multiple lots when used, their correlation with a shipped product lot should be recorded.

6) Documents or data that record traceability information should be given reasonable storage periods and controlled.

7) Each shipping product should have the number of a lot it has originated from marked on it.

8) The procedure for tracing products

Delivery destination -> Target shipped product -> Manufacturing date -> Manufacturing record -> Material use record -> Material acceptance record
-> Used material data, such as ICP analysis data

16. Change Control

Category	Assessment Items	Answer (Choose from the drop-down list)
16. Change Control	10 Do you have definite procedures for change control, including changes and addition of vendors, purchases, and processes? Those changes may arise in manufacturing conditions, production facilities, and tools, and should include changes that will happen within your suppliers and subcontractors as well as within your own company.	No procedure is defined. Although approved rules exist, no change control is implemented. Although no approved rule exists, change control is implemented and its record is preserved. In accordance with approved rules, change control is implemented only internally and its record is preserved. In addition to the above, change control and record preservation are thoroughly implemented also in vendors and subcontractors.
	11 Can you in advance notify us of any changes of chemicals contained in your products and changes described above?	We cannot notify. Although approved rules exist, we cannot in advance notify. Although no approved rule exists, we can in advance notify. Approved rule exist and we can in advance notify.

Change control rules should be established for chemicals contained in products with the following items defined:

1) Change factors that can affect chemicals contained in products include changes and addition of suppliers, changes of purchases, and changes of processes. The change refers to manufacturing conditions, manufacturing facilities, tools, and others of suppliers and subcontractors as well as factories of your own.

2) Items to be verified, verification means, and approval processes should be defined as procedures for inside and outside the company.

3) Change record, notification, and identification information should be defined as part of communication means for inside and outside the company.

A mechanism should exist that enables changes to be verified against our banned and restricted substances list and be reported to us whenever the changes have arisen inside the company, including oversees factories, and in suppliers.

Critical Control Points

1) Criteria for change control of hazardous chemicals, which may be a flow chart, should be definite. Change control rule that fulfill customers' requirements should exist.

2) A mechanism should exist that enforces you to notify our contact of any change, including one arising in the equipment, suppliers, and subcontractors, in raw materials and processes, accompanying analysis data such as ICP data, and obtain an approval for it before implementing it. The change should be verified for compliance with relevant criteria before its implementation.

17. Activities against Failure in Compliance

Category	Assessment Items	Answer (Choose from the drop-down list)
17. Activities against Failure in Compliance	12 Do you have definite procedures for coping with failure to comply with control of chemicals contained in your products?	No definite procedure exists. Approved rules exist, but are not implemented. Although no approved rule exists, procedures have been implemented and the record is preserved. Approved rule exist and procedures have been implemented, though some improvement in corrective actions and/or their record is necessary. Approved rules exist and corrective actions and their record preservation are thoroughly implemented.
	13 Do you have rules established to promptly notify us of failure in compliance that has been found in your products you will deliver to us?	No rule exists. Although approved rules exist, we don't notify. Although no approved rule exists, we can notify. Although approved rules exist, it will take time to notify. Approved rules exist. We can promptly notify, thoroughly record each action, and communicate necessary information.

Procedures for taking actions against failure in compliance with hazardous chemicals control should be defined and rules to notify us of the failure should exist.

Records of failure in compliance should be preserved.

* Control of products, including materials, components, and unfinished products, that have failed to comply with criteria should be implemented to prevent them from being accidentally used or being shipped.

* The actions include identifying the extent of the failure (for example, identifying a lot and equipment that the failure has originated from), preventing the failure from spreading (for example, suspension of shipment or manufacturing), notifying internally, notifying the customer, notifying a person responsible for contained chemicals control, and notifying the management of the business (escalation) as needed.

* Considering the location and department where failure in compliance may arise, the subject product types, and the severity of failure in compliance, procedures to address each case should be established and taken. Records of the actions should be generated and preserved.

Procedure for controlling products that have failed to comply with the criteria

(1) Identifying failed products

Persons who make failed products identifiable and a method for the identification should be defined so that anyone can easily and correctly identify failed products.

(2) Documenting failed products

The details of failure in compliance should be recorded. A format to record the situation of failure development, the extent of failure, actions taken, and others should be defined and used. Generated records should be preserved.

(3) Evaluating failed products

The nature of failure should be evaluated. The evaluation should include the validity of failure and whether organizations have caused the failure.

If the target lot is known, results from the inspection performed for the previous process exist, and it is possible that the next process is affected, a person who evaluates failed products should be defined.

(4) Isolating failed products

If possible, failed products should be isolated in a separate storage location.

(5) Handling failed products

A person who decides how to handle failed products should be defined. The person should consider and decide how failure products should be handled.

The products should be handled in accordance with the decision and the handling should be recorded.

(6) Notifying relevant departments

Departments that may be affected by failed product should be notified.