Guidelines for the management of chemicals in products (CiP)

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Introduction

The Guidelines for the Management of Chemicals in Products specify common management requirements for chemicals in products for the purpose of efficient and reliable implementation of chemical management in the entire supply chain. The Guidelines are introduced with the intention of supporting each organization involved in the supply chain to implement proper management of chemicals in products and to communicate and receive highly reliable information on chemicals in products as the organization refers to the Guidelines.

These Guidelines were reviewed and revised from the Guidelines for Management of Chemical Substances in Products Version 3 issued in August 2012 following the amendment of the Japanese Industrial Standard (“JIS Z 7201 Management of Chemicals in Products - Principles and Guidelines" in December 2017) to which they are compliant.

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1. About the Guidelines for the Management of Chemicals in Products

1.1 The objective of the Guidelines for the Management of Chemicals in Products

The Guidelines for the Management of Chemicals in Products (hereinafter referred to as the "Guidelines") aims to provide practical assistance to organizations engaged in the management of chemical substances contained in products that are the basis for providing products and information on chemical substances contained in their products.

Practicing appropriate management of chemicals in products throughout the entire manufacturing-related supply chain and exchanging information of chemicals in products with high reliability to protect people and the environment has become a social issue.

Originally, the management of chemicals in products was a matter to be implemented subjectively by each organization, however, the Guidelines which are the accumulation of knowledge and experiences of many organizations and industrial bodies are able to offer valuable advice to the organizations practicing chemical management. In cases where the organization already has an existing system or a mechanism of managing chemicals in products, the organization is expected to implement more efficient and assured management while referring to the action items in the Guidelines that are the management requirements.

These Guidelines can be used for self-evaluation of management systems for chemicals in products or for evaluation/confirmation between two parties.

However, it is not the intent of these Guidelines to imply the need for:

– uniformity of actions for the management of chemicals in products
– alignment of relevant documented information such as regulations on the management of chemicals in products to the clause structure of these Guidelines.
– the use of the specific terminology of these Guidelines within the organization.
– establishment of a new or independent management system for management of chemicals in products.

1.2 Scope of Application

The Guidelines provide principles of management of chemicals in products in the respective stage of design and development, purchasing, manufacturing and delivery that should be shared commonly in the entire supply chain, no matter the size, type or maturity of the organization, with the intention that all organizations implementing management of chemicals in products become capable of managing it appropriately and efficiently.

The Guidelines can be referred to by any organization engaged in manufacturing, in other words, any organization which manufactures chemical substances, mixtures, parts and end products as well as a trading house dealing with such products, no matter if is in the upstream, mid-stream or downstream of the supply chain.

The Guidelines do not provide specific chemicals subject to management of chemicals in products and information transfer. In consideration of all organizations involved in the entire supply chain, chemical substances to be controlled shall be determined under the agreement of parties concerned. In addition to laws and regulations, industry standards should also be respected when determining the chemical substances.

1.3 Anticipated Users

Anticipated users are as follows.

(1) The person in charge of developing and verifying the management system of chemicals in products in the organization

When establishing the management system of chemicals in products in each organization, the organization may refer to these Guidelines.

In the stage of developing the management system, the person in charge can pursue his duties while referring to these Guidelines. After the system is set up, the Guidelines can be used as an in-house education tool and the organization can inform and disseminate the requirements for the management of chemicals in products.

If the organization already has a management system of chemicals in products that is established in accordance with other equivalent or higher criteria and guidelines, the organization shall verify that the current management can satisfy the management requirements stated in these Guidelines. Where necessary, the organization shall carry out improvement of the management system to meet its needs. In such cases, the organization may refer to these Guidelines.

The organization can also utilize them when it conducts internal audits for self–assessment to verify if the management system for chemicals in products is functioning appropriately.

(2) Person in charge of verifying the management system of chemicals in products at the supplier

When the external organization such as a purchaser or a customer verifiers the suppliers if their management system of the chemicals in products is properly developed in the supplier, the person in charge can refer to these guidelines.

1.4 Unit of Management of Chemicals in Products

The unit of management of chemicals in products envisioned in the Guidelines is not “products,” but “organization.” In the Guidelines, “organization” indicates a company, a corporation, plant or department, individual business holder, a part or a combination of the above.

Example: XX Corporation, XX Plant, YY Inc., YY Division, ZZ Group, ZZ Product Division

1.5 Operation Flow of the Guidelines for the Management of Chemicals in Products

To operate along the Guidelines, the following flow is recommended.

(1) Development of the Management System of Chemicals in Products

Each organization involved in the supply chain shall develop a management system for chemicals in products within the organization. Although the best form for a management system varies depending on the type of industry, type of business and business content, the organization can refer to these Guidelines whether utilizing an existing management system or developing a new management system.

(2) Evaluation of the Management System of Chemicals in Products

The organization shall evaluate if its management system for chemicals in products satisfies management requirements stated in Guidelines.

To evaluate conformance to the action items, the organization can refer to “6. Evaluation in accordance with the Guidelines for the Management of Chemicals in Products and Self-Declaration of Conformance.” Evaluation can be implemented efficiently and objectively if the organization uses the “Check Sheet.” It is important that the management systems is sustained and improved whenever necessary.

(3) Declaration of development of the management system for chemicals in products

As a mode of announcing to the community including external organizations such as the purchaser that the organization has developed the management system satisfying the action items that are requirements to manage chemicals in products, the Guidelines recommend the organization to issue self-declaration of conformance. For the judging criteria of conformance with the action items or self-declaration of conformance, the organization can refer to “6. Evaluation in accordance with the Guidelines for the Management of Chemicals in Products and Self-Declaration of Conformance” in the Guidelines.

1.6 Integrating to the Existing Management System

When the organization already has a management system for quality management, environmental management etc., depending on the judgment of the organization, the organization may optimize the existing management system to be integrated with the management system for chemicals in products.

While it is possible to develop a new management system, it is recommended to utilize and efficiently optimize the existing management system where there is one. It is, however, necessary that such a management system substantially satisfies the action items stated in the Guidelines.

For comparison of the action items of the Guidelines with the requirements of ISO 9001:2015 (JIS Q 9001:2015) and ISO 14001:2015 (JIS Q 14001:2015), please refer to Annex A: Comparison with the Quality and the Environmental Management Systems and JIS Z 7201.

1.7 Positioning the Guidelines for the Management of Chemicals in Products against JIS Z 7201

JIS Z 7201:2017 is to prescribe principles and guidelines for management of chemicals in products, but not to serve as requirements for evaluating conformity. “4.8 Evaluation of management system for chemicals in products” of the Standard refers to “In the supply chain, in some cases, the organization is required to verify if the management of chemicals in products is appropriately conducted in the organization. In this regard, the industrial organization may compile the documentation on requirements for the management system of the chemicals in products that are relevant to principles and guidelines set forth in this Standard, and facilitate the organization which practices the management of chemicals in products to evaluate and to declare conformity.”

These Guidelines are regarded as the document that was created based on the above description. Providing the action items that are requirements for management of chemicals in products in compliance with guidelines stated in JIS Z 7201:2017, the Guidelines enable the organization to evaluate conformance to the action items and issue a self-declaration of conformance to the management system.

1.8 Self-Declaration of Conformance in accordance with Guidelines for the Management of Chemicals in Products

Self-declaration of conformance based on the Guidelines indicates the organization’s manifestation and commitment to the following status:

(1) The organization has developed the management system along the Guidelines and is operating it, or

(2) The organization has established the management system in accordance with other criteria or other guidelines that are at the equal or higher level compared to these Guidelines and such a management system in implementation practically satisfies management requirements for chemicals in products. Specific criteria and methods of self-declaration of conformance are shown in “6. Evaluation in accordance with the Guidelines for the Management of Chemicals in Products and Self-Declaration of Conformance.”

It is important that self-declaration of conformance is issued earnestly and seriously by many organizations, and accepted and well respected by the customers. In this way, the self-declaration of conformance can be operated effectively and developed further.

1.9 Revision/Abolition of the Guidelines for the Management of Chemicals in Products

As these Guidelines were prepared in compliance with JIS Z 7201:2017, document management shall be carried out as follows, dependent on the continuance (verification), amendment or abolition of the Standard by review based on Industrial Standards Law.

(1) If the Standard is continued (verified), these Guidelines will automatically continue.

(2) If the Standard is amended or abolished, a collaborative review committee shall be established to examine revision or abolition of the Guidelines. The review committee shall be composed of participating bodies of the Edition 4 Collaboration Committee, but participation shall be based on the intentions of each body. The collaborative review committee shall be established with the participation of one or more bodies. The Guidelines will be abolished if the examination is not carried out despite one year having elapsed after the amendment or abolition of JIS Z 7201:2017. Regarding a proposal for revision etc. from the participating bodies of the Edition 4 Collaboration Committee, it shall be possible to establish a collaborative review committee to examine the proposal, if one-half or more (for 11 bodies, 6 or more) of the participating bodies of the Edition 4 Collaboration Committee agree (excluding bodies whose intentions cannot be confirmed due to dissolution etc.).

In all the above cases, participation of new organizations etc. in the collaboration committee shall be accepted by approval of more than one-half of the participating organizations of the collaboration committee.

2. Referential Standards of the Guidelines for the Management of Chemicals in Products

As mentioned above, the Guidelines are in compliance with "JIS Z 7201: 2017 Management of Chemicals in Products - Principles and Guidelines." Additionally, the Guidelines also refer to standards as shown in Table 2-1.

Table 2-1: Referential and compliance standards for Guidelines for the management of chemicals in products

Management of chemicals in products	– JIS Z 7201:2017 Management of Chemicals in Products – Principles and Guidelines

Management systems related	– JIS Q 9000:2015 Quality management systems – Fundamentals and vocabulary (ISO 9000:2015 Quality management systems – Fundamentals and vocabulary) – JIS Q 9001:2015 Quality management systems – Requirements (ISO 9001:2015 Quality management systems – Requirements) – JIS Q 14001:2015 Environmental Management System – Requirements with guidance for use (ISO 14001:2015 Environmental Management System – Requirements with guidance for use) – ISO/IEC Directives, Part 1, Consolidated ISO Supplement Procedures specific to ISO Annex SL
Self-declaration of conformance	– JIS Q 17050-1:2005 Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements (ISO/IEC 17050-1:2004 Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements)

The initiatives indicated by these Guidelines as action items share many commonalities with the processes of the quality management systems or the environmental management systems that organizations implement. For the action items, therefore, considering the affinity of the structure with other management system standards, these Guidelines refer to the higher structure of the management system of ISO/IEC Directives, Part 1, Consolidated ISO Supplement – Procedures specific to ISO Annex SL, which are adopted in ISO 9001:2015 (JIS Q 9001:2015) and ISO 14001:2015 (JIS Q 14001: 2015). Furthermore, for the processes of "5.5 Operation," reference is made to the Section 8 "Operation" part of Quality Management Systems ISO 9001: 2015 (JIS Q 9001: 2015).

Check the standard text for the referenced standards.

3. Definition of Terms

For the main terms and definitions used in this Guideline, in addition to ISO 9001:2015 (JIS Q 9001:2015), the following terms of JIS Z 7201:2017 are used.

Terms	Definition (underlined are defined terms)
Chemical substance	A chemical element or compound that either exists in nature or is obtained through a manufacturing process.
Mixture	A mixture intentionally comprising two or more chemical substances Note: Examples are paints, inks, alloy ingot, solder, resin pellets containing additives, etc.
Chemicals	Chemical substance or mixture.
Article	An item of specific shape, appearance or design created during manufacture which substantially determines functions in final use rather than functions provided by its chemical composition (refer to 4.5) Note: Examples of articles are metal plates, gears, integrated circuits, electric appliances, transport equipment, etc.
Part	An article to be manufactured until it turns into an end product. Note: The followings are examples of parts. a) Examples of parts which are the first article converted from a chemical product are shown below. – Personal computer: a single key mounted in a keyboard – Electronics device: a resin casing for a telephone set – Transport equipment: an automobile brake pad – Machine tool: a copper material for a motor – Furniture: a steel material for parts a spring b) Examples of parts manufactured by assembly are shown below. – Personal computer: a personal computer keyboard – Electronics device: a telephone receiver – Transport equipment: an automobile brake – Machine tool : an electric drill motor – Furniture: a bed mattress
End product	An end product is the final article which is the outcome of assembling, processing or manufacturing chemical products and/or parts. Note: The following are examples of end products. – Personal computer: a personal computer – Electronics device: a telephone set – Transport equipment: an automobile – Machine tool: an electric drill – Furniture: a bed
Product	A product is a chemical product, a part or an end product which is delivered to a customer as the outcome of business activities of the organization. Note: In some cases, a packaging material used to pack a product or a protective material is also included in the product.
Organization	Group with its own functions involving responsibility, authority and interrelationships.
Supplier	An organization which delivers products to the downstream.

Terms	Definition (underlined are defined terms)
Customer	An organization which receives products from the upstream. Note: Consumers are not included as a customer in the Guidelines.
Delivery	Delivery is the act of sending out products to a customer. Note 1: In ISO 9001:2015 (JIS Q 9001:2015), “release” is also used as a similar term besides the term of “delivery,” however “release” also implies delivering to the next process internally in the organization. Hence, these Guidelines use the term “delivery” to define when an organization sends out products to a customer. Note 2: ‘Delivery” is also expressed as shipping. Note 3: Organizations that deliver include trading companies.
Supply chain	A chain to interconnect suppliers and customers.
Chemicals in products	Chemical substances which are known to be contained in products Note: Sometimes abbreviated as CiP (Chemicals in Products).
Industry standard	Criteria for managing chemicals in products which are drawn and publicized by the organization of the respective industry.
Management criteria for chemicals in products	Criteria defined by the organization in compliance with laws, regulations and the industry standards relevant to chemicals in products. Note 1: In general, the management criteria for chemicals in products include the list of declarable chemical substances, the management level (restriction of inclusion, information management, etc.), the scope of application, etc. Note 2: The management criteria for chemicals in products include the law or the regulation notified by the customer to comply, and the industry standards of the customer that are agreed to comply between the customer and the organization.
Information of chemicals in products	Information on chemicals which are subject to the management criteria for chemicals in products.
Traceability	The ability to track history records concerning purchasing, manufacturing and delivery of the product.
Interested party	Individual or organization that can affect, be affected by, or perceive itself to be affected by certain decisions or activities. Note 1: Examples of interested parties related to the management of chemicals in products include customers, suppliers, outsourcing organizations, administrative offices and people within the organization. Note 2: The term "stakeholder" is a synonym which represents the same concept.

Terms	Definition (underlined are defined terms)
Risk	Effect of uncertainty on objectives. Note 1: An effect is a divergence (deviation) from expectation, in a desired or undesired direction. Note 2: Uncertainty is the state, even partial, of deficiency of information, understanding or knowledge related to, an event, its consequence, or likelihood. Note 3: Although the risk has not yet occurred, the possibility of future occurrence is targeted. It is also not intended for specialized, statistical and scientific risk. Note 4: The term risk is widely used in general, but the concept may differ in each field. In these Guidelines, risk is distinguished from "chemical substance risks" and is used as a term indicating the effect of uncertainty on management of chemicals in products.
Opportunity	Something that, at a timing convenient for actions to achieve the objectives of the organization, depending on the circumstances, can bring about a desirable effect for the organization. Note: For an event that has already become clear, it is the situation or state that is advantageous for achieving it. It is not a concept opposite to risk.

The following terms are uniquely defined and used in these Guidelines.

Terms	Definition (underlined are defined terms)
Conformity	Satisfying the management criteria for chemicals in products Conformity as a result of evaluating the management system for chemicals in products in accordance with the Guidelines means complying with the action items.
Nonconformity	Is not fulfilling the management criteria for chemicals in products and such a product is called a 'nonconforming product'. Nonconformity as a result of evaluating the management system for chemicals in products in accordance with the Guidelines means not complying with the action items.
Parallel production	During any process of receiving inspection – warehouse storage – manufacturing – WIP (Work In Progress) / end-products warehouse storage – delivery, products that are restricted to contain specific chemical substances are being manufactured, while other products are also manufactured using chemical products or parts containing the above specific chemical substances in the same factory building at the same time.
Outsourcing organization	External organization which is assigned to undertake all or a part of operations or functions of the organization.

4. Principles of the Management of Chemicals in Products

It is important that the organization involved in the management of chemicals in products should develop, implement, maintain and evaluate the management system upon understanding the principles of the management of chemicals in products.

4.1 Necessity for management of chemicals in products

Products that utilize or apply the properties of chemical substances bring advanced civilization to human society, but the potential to impact people and the environment, the so-called "chemical substance risk," is also a reality. Chemical substance management is required to be applied throughout the life-cycle of a chemical substance based on the risks of the chemical substance considering the hazards of the substance and the amount of exposure to the substance, and laws and regulations on chemicals in products for the finished products are enacted in each country and region around the world. As a response, chemical substance risks can be lowered by switching to safer chemical substances or by reducing exposure. In line with such trends, the movement to request the management of chemicals in products and the disclosure and transmission of such information has spread internationally.

In many cases, it is not easy to understand the chemicals in a product unless they manufacture a part constituting the product or the original material, and for all organizations involved in manufacturing throughout the supply chain, understanding through transmission of information on chemicals in products is an important issue. Information such as content, obtained in management of chemicals in products, can also serve as basic information when evaluating exposure levels.

4.2 Fundamentals of the management of chemicals in products

As the principles of the management of chemicals in products, each organization shall define the management criteria of chemicals in products for the respective stage of purchasing, manufacture and delivery during design and development. The organization shall also verify if management is implemented properly in accordance with the management criteria. It is important that such a management is implemented in the entire supply chain and the information is communicated according to the management criteria.

For the purpose of producing products which can fulfil the management criteria of chemicals in products, the organization shall operate the management of chemicals in products respectively in the stage of design and development, purchasing, manufacturing and delivery as shown in Table 4-1. Depending on the type of business operation, some organizations may not have all stages covering from design and development, purchasing, manufacturing to delivery.

The design & development stage, purchasing stage, manufacturing stage, and the delivery stage refer to each function of operations, namely, the design & development, purchasing, manufacturing, and delivery functions and activities. And even if they do not match the names used in the organization, the management criteria apply to the corresponding function or activity.

Table 4-1: Management of chemicals in products at the respective stage of operation

Stage	Action Item
Design and development	For the purpose of producing products which can fulfil the management criteria of chemicals in products, the organization shall define the management criteria of chemicals in products after considering the action items to be implemented at the respective stage of purchasing, manufacturing and delivery, corresponding to products and the type of business operation of the organization.
Purchasing	In accordance with the management criteria of chemicals in products for purchasing, the organization shall issue a purchase order to a supplier, and collect information of chemicals in products to be purchased from the supplier. The organization shall manage that products to be purchased should satisfy the management criteria of chemicals in products for purchasing.
Manufacturing	The organization shall manage chemicals contained in products while focusing on a change of concentration, a change of composition or other changes in accordance with the management criteria of chemicals in products for manufacturing.
delivery	The organization shall verify that products to be delivered should satisfy the management criteria of chemicals in products.

It is important that chemicals in products be managed scientifically and rationally. For example, in the processes of conversion from chemical products to articles, new articles are produced by phenomena such as volatilization, curing, precipitation, melting, etc. In the course of these processes, it is necessary to scientifically understand what kind of situation the chemicals in products are in depending on the chemicals, raw materials and manufacturing conditions that are input to the manufacturing process, that they be managed in a viable manner that can be implemented, and for information on chemicals in products to be understood and maintained.

Compliance relating to chemicals in products is an important issue not only to avoid impacts on people and the environment caused by chemicals in products but also from the viewpoint of maintaining business continuity. A nonconformity to management criteria for chemicals in products may not only affect direct business, but if shipped as part of an end product, there is also the possibility that effects such as cease of sales, recall from the market, etc. will occur. It is necessary to properly understand the content of laws and regulations that lay the foundation for the management criteria for chemicals in products, recognize them as an important issue for the organization, and work on the activities of management of chemicals in products.

Trading companies that do not manufacture or directly handle products for the organization are also fundamental to the management of chemicals in products, in appropriately understanding chemicals in products and communicating information in the supply chain. It is necessary to take actions in line with the type of business, such as obtaining information of chemicals in products, providing information, and managing handling and delivery within the organization.

4.3 Actions to address risks and opportunities in management of chemicals in products

As shown in “3. Definition of Terms,” risk is the “effect of uncertainty on objectives,” and uncertainty is the state, even partial, of deficiency of information, understanding or knowledge related to, an event, its consequence, or likelihood. An effect is a divergence (deviation) from expectation, in a desired or undesired direction. It indicates the concept of having an effect on the effectiveness of management of chemicals in products. Opportunities are convenient times for actions to achieve organizational objectives and depending on the circumstances can bring about a positive impact on the organization. The concept is not the opposite of risk.

A risk in management of chemicals in products is, for example, the occurrence of a nonconformity, and the influential and indirect effects of that also have a possibility of affecting business such as product recalls, compensation for damages, and suspension of transactions. Examples of such actions towards risk in the management of chemicals in products include preventive measures to eliminate possible nonconformities, analysis of nonconformities that have occurred, reflection of analysis results, and other such measures to prevent recurrence.

Opportunities related to the management of chemicals in products include, for example, research and development of new products, production facilities and information systems for adoption of newly established & updated or new parts, and responses to changes in laws and regulations related to chemicals in products. Using these to tackle the management of chemicals in products can raise evaluations from customers of the organization, develop products that comply with regulations on chemicals contained in products, and may produce a desirable situation that enables continued efficient production. Actions towards opportunities may also include consideration of relevant risks.

4.4 Management of chemicals in products based on risk

The products and business types of the organizations that make up the supply chain are diverse, and various risk factors for the management of chemicals in products can be considered. Each organization should use the knowledge of its specialized field to identify, analyze and evaluate risks in the management of chemicals in products to clarify the issues, take appropriate measures to prevent or reduce risks, and practice management of chemicals in products.

Examples of risk in the management of chemicals in products include changes in laws and regulations relating to chemicals or changes to management criteria for chemicals in products for customers, as well as changes, misuse, contamination, etc. of chemicals in products that are provided from externally.

It is important to consider the magnitude of the problem at the time of occurrence and its occurrence rate, and, according to the type of business, with priority and preference identify the items to be managed from within the organization's own processes, and implement appropriate and efficient management. Reference procedures to identify items for priority management are given below. Items for priority management can be a part of the action items stated in "5. Action Items for Management of Chemicals in Products" or in some cases, they are related to multiple action items.

(1) Verification of risks in handling chemicals and in management of chemicals in products
  – Verify chemical products, parts, secondary material, etc.
  – Verify production equipment, jigs, etc.
(2) Identification of items for prioritized management
  – Identify items for prioritized management in consideration of risks in management of chemicals in products.
  – Determine the management level (specific response) for prioritized management and other general management.

It is important that the organization having specialized and detailed knowledge of chemical products, parts and the manufacturing processes used in the organization determines the items for prioritized management and its response to those items under its own responsibility. Furthermore, it is necessary that the organization expresses the basis of selecting those items and requests cooperation in management to the upstream and downstream organizations. Table 4-2 below provides items which generally require prioritized management. If needed and if possible, the organization advisably carries out management of chemicals in products in cooperation with the organization which holds relevant knowledge and experiences.

Table 4-2 Examples of items considered to require prioritized management

Examples
○ When using chemical substances whose inclusion may be subject to regulation under future regulations, or chemical products or articles that contain such chemical substances; – continuously monitor the regulatory status of the chemical substance and examine alternatives as necessary. ○ When chemical substances whose inclusion has become newly restricted by laws and regulations are used in the company's own manufacturing processes; – response towards examination of alternative products, changing amounts used, usage and destination country restrictions etc. is required. ○ When using purchased items that are likely to contain chemical substances whose inclusion has

Examples
become newly restricted by laws are regulations; – confirm presence/absence and content of regulated chemical substances, and carry out the same examination as above as necessary. ○ When there are parts in stock that contain chemical substances whose inclusion is restricted by new laws and regulations; – thorough prevention of misuse and contact contamination. ○ When using chemical products which contain declarable chemicals under the management criteria of chemicals in products; – thorough management of the content of the controlled chemical substance during the company's own manufacturing processes and in its own products. Also consider alternatives as necessary. ○ When using chemical products which may contain declarable chemicals under the management criteria of chemicals in products; – confirm presence/absence and content of controlled chemical substances, and carry out the same management as above as necessary. ○ When manufacturing different products with the same manufacturing equipment; – fully wash the reaction vessel etc. so that the previously produced raw material does not remain and thoroughly manage the prevention of contamination to the product to be manufactured subsequently. ○ Conversion process from chemical products to articles; – when chemical products contain a controlled substance, thoroughly manage the contained amount of the chemical substance in the article. ○ When using recycled materials, in particular, open-recycled materials; – confirm presence/absence and content of controlled chemical substances subject to management. ○ When using minerals and natural products; – confirm presence/absence and content of controlled chemical substances subject to management. ○ Processes using chemical products which require prioritized management – thoroughly manage the content of the controlled chemical substance during the company's own manufacturing processes and in its own products. ○ Parts made from chemicals manufactured in manufacturing processes requiring prioritized management ○ Processes using parts which require prioritized management ○ Parallel production (manufacturing of products with differing management criteria for chemicals in products in close proximity) processes – thorough prevention of misuse and contamination. ○ Processes with a possibility of migration contamination via contact

In some cases, depending on the type of products or where the product is delivered, some products are not applicable to regulations or some use of the product is exempted from regulations restricting inclusions. Therefore, the organization is required to know if there is a parallel production, which is to have a manufacturing process using restricted chemicals, while there is also a manufacturing process not using the said restricted chemicals. In case that a parallel production exist, it is required that the organization carry out intensive management of chemicals in products to prevent contamination of such a chemical substance by incorrect use.

"Annex B: Parallel Production" shows a diagram of parallel production.

4.5 Conversion Process to Article

For managing chemicals in products in the entire supply chain, it is crucial to manage chemicals contained in parts which are the first articles to be converted from chemical products.

Specifically, it is necessary that not only identifying the chemical mass contained in chemical products that are used to manufacture parts to convert to first articles from chemical products, but also managing

a change in chemical mass and/or physical or chemical changes during the conversion processes to an article. Furthermore, managing prevention of contamination is also necessary.

Figure 4-1 shows the image of conversion process from chemical products to articles in the supply chain and Table 4-3 shows examples of conversion process from chemical products to articles.

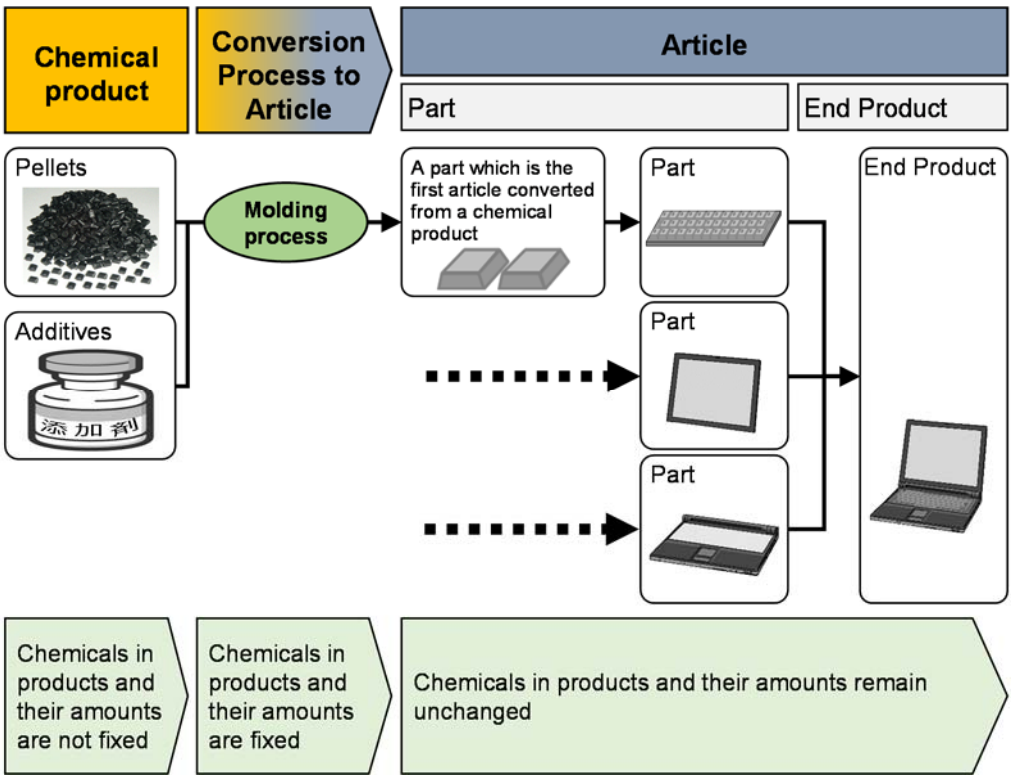

Figure 4-1 Conversion process from chemical products to articles in supply chain

Table 4-3 Example of conversion process from chemical products to articles

Conversion process	Chemical product to be used	Material to be processed (article)	New article	Phenomenon
Painting	Paint	Base material	Painted base material	Volatilization: Some or all components of original chemical substances contained in a chemical product are removed by evaporation (subtraction processing)
Printing	Ink	Base material	Ink printed product	
Printing/baking	Glass paste	Base material	Pattern- formed glass substrate	
Synthetic adhesion	Adhesive	Base material	Plywood	
UV printing	UV ink	Base material	UV-ink printed product	Hardening: Original chemical substances converted to different substances and become hardened (not addition, but a process of conversion takes place)
Epoxy sealing	Epoxy resin	Sealed chip	Sealed semiconductor chip	
Plating	Plating fluid	Base material	Plated Base material	Precipitation: A phenomenon in which multiple components of chemical substances contained in a chemical product change mutually and part of the substances appear on the surface of the existing article in a solid form (not an addition, but a conversion process takes place)
Plastic molding	ABS pellet	-	ABS plastic casing	Fusion: a heating process to melt originally solid chemical products to a liquid state in order to change the physical profile (in many cases, composition of chemical product does not change)
Soldering	Solder	Mounted substrate	Soldered mounted substrate	
Die casting	Alloy ingot	-	Die-cast part	

4.6 Framework for management of chemicals in products

Based on principles of “4.2 Fundamentals of the management of chemicals in products” and “4.5 Conversion Process to Article” in the Guidelines, the management of chemicals in products in the entire supply chain can be classified into seven frameworks. Out of seven frameworks, the organization shall select and confirm the framework which is relevant to its products or its business operation. It is recommended that the organization carries out management based on guidelines of such a framework.

Management of chemicals in products shall be carried out at each stage of design and development, purchase, manufacture and delivery, but management criteria relating to chemicals in products in the later stages shall be clarified in the design & development stage, based on the management criteria for chemicals in products.

Each manufacturing process in the organizations associated with the supply chain can generally be classified into “manufacturing process of chemical products,” “manufacturing process for manufacturing articles from chemical products,” “manufacturing process of parts” and “manufacturing process of end products.” It is important to prescribe management methods for each, but with purchasing, manufacturing and delivery considered as unit processes, the management methods of each manufacturing process can be summarized on the basis of the unit processes.

The important thing is to understand whether the state of the chemical substance handled in each unit process is a chemical product or an article and to manage accordingly. When the aspect of the chemical-substance state is incorporated into the unit processes of purchasing, manufacturing and delivery, all processes can be classified into six management frameworks; i.e. purchasing chemical product (Management framework I), manufacturing chemical product (Management framework II), delivery of chemical product (Management framework III), purchasing article (Management framework IV), manufacturing article (Management framework V) and delivery of article (Management framework VI).

The management methods shall be determined by setting them based on these six management frameworks. Organizations engaged in the management of chemicals products need to address the applicable frameworks among management frameworks I-VI. Management framework VII is common management, and targets all organizations engaged in management of chemicals in products (refer to Figure 4-2).

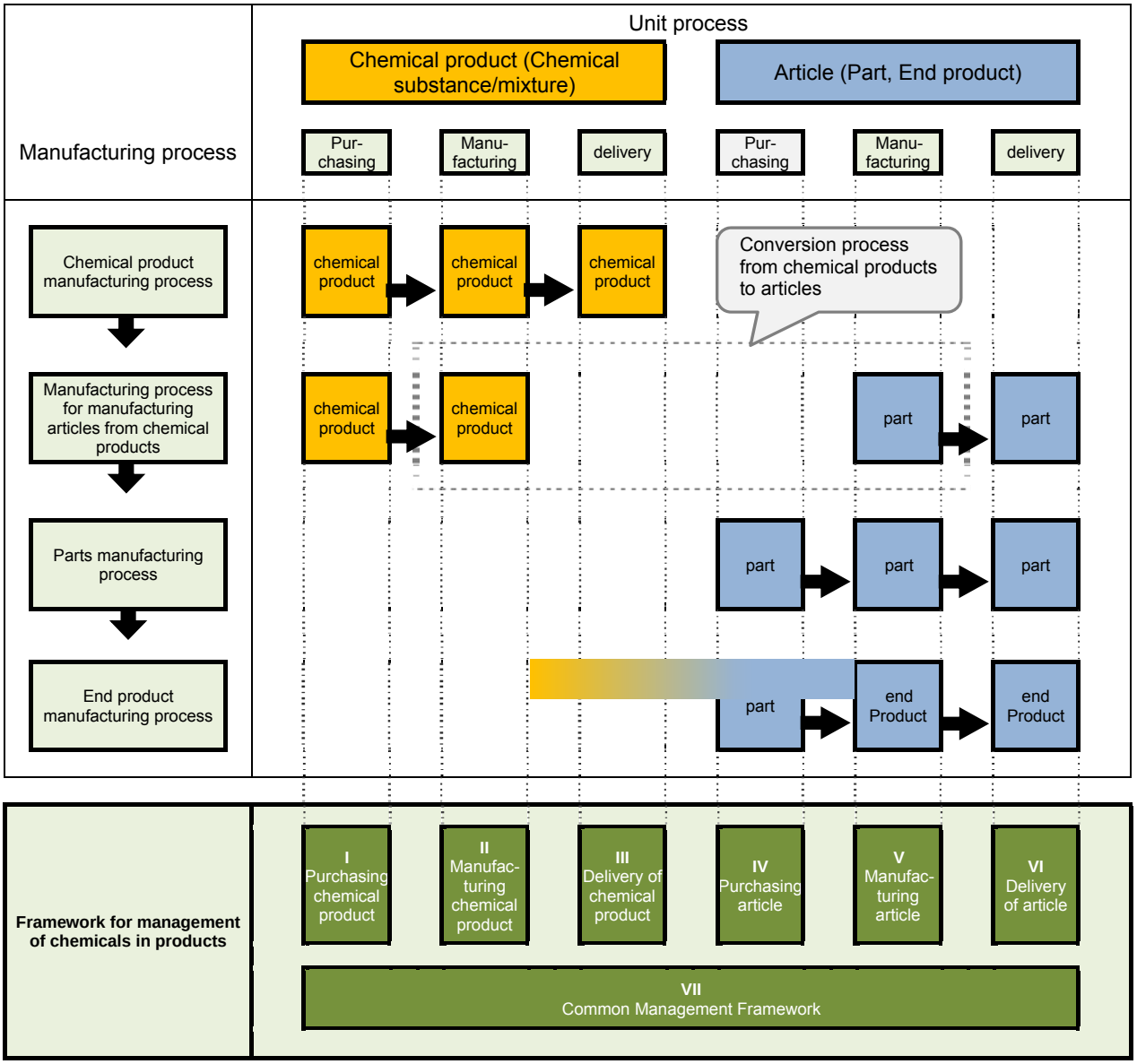

Fig 4-2 - Seven frameworks for management of chemicals in products

Action items corresponding to the seven frameworks for management chemicals in products are shown in Annex C.

4.7 Maintenance of Information of Chemicals in Products

With the management of chemicals in products being conducted at the respective stage of design and development, purchasing, manufacturing and delivery as a prerequisite, all organizations involved in the supply chain shall compile information on chemicals in products based on rational information at each stage and provide such information to the next organization.

Generally, information of chemicals in products in an organization shall be compiled by the organization itself based on information of chemicals in purchased products and based on manufacturing information or scientific knowledge and experience on manufacturing processes. As shown in Figure 4-3, the mid-stream or downstream organization in the supply chain shall compile and prepare information of chemicals in products to be delivered.

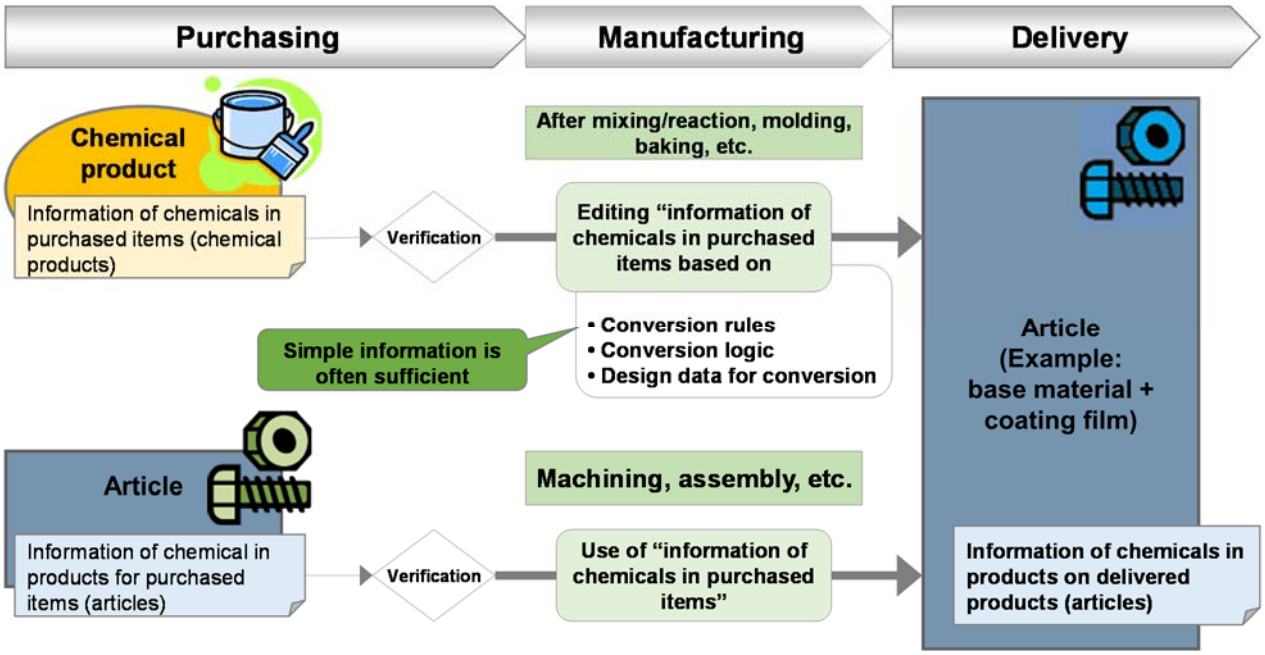

Figure 4-3 Maintenance of information of chemicals in products in mid-steam and downstream of the supply chain

4.8 Responsible communication of information of chemicals in products

Information of chemicals in products that the organization provides for products delivered to customers must be accurate information so that customers can handle the products appropriately. Therefore, based on information from suppliers and their own knowledge, organizations should collect and maintain information on chemicals in products via the best possible endeavors and communicate them to customers according to organizational standards and procedures. Information of chemicals in products is information related to compliance and it is necessary to properly understand the standards to be observed and to meet the specified requirements level.

4.9 Support for organizations where autonomous management is difficult

It is essential that all organizations involved in the entire supply chain should carry out management of chemicals in products appropriately. As a consequence, a product manufactured through the supply chain will be able to achieve compliance with laws and regulations on chemicals in products.

In actual fact, however, many organizations find it difficult to carry out autonomous management of chemicals in products such as managing data or chemical reactions. In particular, mid-stream organizations which are the key of communicating information of chemicals in products are facing difficulty in autonomous management.

It is therefore very important that all organizations involved in the supply chain understand requirements for management of chemicals in products stated in the Guidelines, and that upstream and downstream organizations provide supports to implement the appropriate management.

4.10 Consideration to Corporate Confidentiality

Although the information of chemicals in products must be disclosed to comply with international or domestic laws and regulations, it is also essential for the organization to keep corporate confidentiality in order to sustain healthy competitiveness of the organization. In particular, it is a great concern for the product suppliers that disclosing the information on chemicals in products in chemical products or articles may lead to a serious business issue for them. Therefore, sufficient consideration is necessary to handle corporate confidential information between organizations that purchase from each other when they transfer or receive information of chemicals in products. In some cases, corporate confidential information also includes commercial and business information such as distribution channels or names of purchased products.

5. Action Items for Management of Chemicals in Products

The action items that are the compilation of what to be implemented in management of chemicals in products are shown in the following pages. A list of action items is shown in "Annex D: List of Action Items." In addition, "Annex E: Check Sheet" can be used to evaluate whether or not the management system for chemicals in products is properly developed and operated in the organization using the Guidelines.

The action items are structured and described in a PDCA format. PDCA refers to P (Plan: formulating policies, planning), D (Do: implementing plans and performing operations), C (Check: evaluating performance and reporting the result) and A (Act: implementing measures for continuous improvement) where a cycle of actions are continuously implemented. Additionally, rules shall be established to satisfy requirements of the action items and the organization shall operate the action items according to established rules.

Action Items	The action items are the list of items required for managing chemicals in products and consist of items from "5.1 Context of the organization" to "5.6 Performance evaluation and improvement"
	The specific kinds of management that should be practiced for the action items are described. It is important that action details are described commonly for the entire supply chain. However, depending on the nature of business operation, they may not be sufficiently explained. In such a case, management should be implemented to match the nature of business of the organization after the organization has good understanding of the required management level and the intent of "Notes." If necessary, the organization may replace the management description. Since there is a diverse range of industries involved in the supply chain, it is advisable that detailed explanatory materials be prepared to cater for different sectors. In case that "the action item" does not apply to the organization, the organization does not need to satisfy the said action item.
Note:	Referring to notes stated in Guidelines of JIS Z 7201:2017, description of action items, points of management and examples of the management are provided herein.

5.1 Context of the organization

5.1.1 Understanding the organization and its context

The organization shall clarify external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its management of chemicals in products.

Note:

(1) An issue is a changing surrounding situation that has the possibility to affect an organization tackling the management of chemicals in products, examples of which include the following.
   a) External issues include domestic and overseas regulatory, technical and economic conditions relating to chemicals in products, recognition and values of external stakeholders and effects of product life-cycle (EOL: End of Life).
   b) Internal issues include the characteristics or circumstances of the organization such as governance and organizational structure, products, competence (people, knowledge, processes etc. involved in the management of chemicals in products, knowledge, processes), and it is important to recognize that all departments involved in design & development, purchasing, manufacturing and delivery are required to manage chemicals in products.

(2) The issues clarified contribute to the effectiveness of the activities of each of "5.1.3 Determining the application scope of management of chemicals in products," "5.3.1 Actions to address risks and opportunities" and "5.6 Performance evaluation and improvement."

5.1.2 Understanding the needs and expectations of stakeholders

The organization shall clarify the following items to understand the needs and expectations of stakeholders.

a) The stakeholders closely related to the management of chemicals in products
b) The requirements of those stakeholders that are closely related to the management of chemicals in products

Note:

(1) Examples of external stakeholders related to the management of chemicals in products include customers, suppliers, outsourcing organizations, industry groups, and administrative offices.

5.1.3 Determining the scope of application of management of chemicals in products

The organization shall determine the appropriate scope of application of management of chemicals in products.

When determining this scope, the organization shall consider.

a) The external and internal issues for the organization defined in 5.1.1
b) The requirements of stakeholders defined in 5.1.2
c) The relationship between the organization and chemical substances
d) The externally provided products handled by the organization and the products delivered to external parties

The scope of application of management of chemicals in products shall be put in a state that can be used as documented information.

Note:

(1) In considering the organization's relationship with chemicals, the seven frameworks (see 4.6) of the management of chemicals in products can be referenced.
(2) For products handled by the organization, the following kinds of products that may become a cause of contamination even without constituting a product can be included and subject to contamination measures.
    a) indirect packaging materials (for example, parts packaging materials, protective materials, etc.)
    b) supplementary materials (for example, grease, release agents, etc.)
    c) tools and jigs
(3) The scope of application of management of chemicals in products includes the scope of acquisition of information of chemicals in products and the scope of systematic management including the countermeasures against contamination in (2).

5.1.4 Implementation of the management of chemicals in products

The organization shall establish, implement, sustain and continuously improve the systems for the management of chemicals in products in accordance with the principles and action items for the management of chemicals in products stated in the Guidelines.

For the purpose of producing products which can fulfil the management criteria of chemicals in products, the management of chemicals in products shall be carried out according to the type of business operations of the organization at each stage of design and development, purchasing, manufacturing and delivery.

Note:

(1) It is important to clarify the necessary inputs (resources and information) and the expected outputs (deliverables including information) at each stage of design & development, purchasing, manufacturing and delivery.
(2) Organizations that have developed management systems such as quality control and environmental management may practice management that satisfies the action items indicated by the Guidelines by utilizing existing mechanisms or by incorporating into the mechanisms.

5.2 Leadership

5.2.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the management of chemicals in products by.

a) Taking accountability for the effectiveness of the management of chemicals in products.
b) Positioning the management of chemicals in products as an activity of the organization.
c) Making the necessary resources available for use (Refer to 5.4.1).
d) Ensuring compliance with the management criteria for chemicals in products.

5.2.2 Policy

The top management shall establish the management policy of chemicals in products for the organization and shall formulate, implement and sustain plans based on that policy. Furthermore, the top management shall state that it will appropriately implement the management of chemicals in products.

Note:

(1) Implementation of management of chemicals in products refers to development of a management system for chemicals in products according to JIS Z 7201:2017 and these guidelines.
(2) It is important to confirm that policies approved by top management are disseminated and understood by those concerned.
(3) It is important that responses to the industry standards or compliance with regulations are incorporated into the policies.
(4) It is important that the policies are reviewed as required at the time of amendment of laws and regulations and maintained constantly.
(5) As examples of dissemination, the organization can assemble persons in charge and explain about policies, put up posters, distribute the cards explaining about policies or announce in the information sharing system within the organization.
(6) In the management policy for chemicals in products, it is also effective to set "compliance with laws and regulations related to products and response to industry standards," in accordance with these Guidelines, in management systems already operated in the organization.

5.2.3 Resources, Roles, Responsibility and Authority of an Organization

In order to implement effective management of chemicals in products, the top management shall define the responsibilities and authorities for the relevant roles and communicate this within the organization.

Note:

(1) It is necessary for top management to allocate responsibility and authority for the following matters and to evaluate and improve via "5.6 Performance Evaluation and Improvement" to ensure improvement.
    a) Ensuring that each process (department) produces the intended results.
    b) Reporting performance and improvement opportunities for management of chemicals in products periodically, especially to top management.
(2) Clearly defined responsibilities and authorities mean that it is agreed that departments and roles have been clearly determined.
(3) It is important that the scope of responsibilities and authorities should also be clearly defined in the outsourcing organizations. For outsourcing, refer to “5.5.4.4 Verification of the Management Status of Chemicals in Products at Outsourcing Organizations”.
(4) For instance, the organization chart or rules for management of chemicals in products can be used as a method of clarification.
(5) The roles of management of chemicals in products may also be defined in the framework of the environment management system or the quality management system.

5.3 Plan

5.3.1 Actions to address risks and opportunities

When formulating a plan for the management of chemicals in products, the organization shall consider the external and internal issues for the organization defined in 5.1.1, the requirements of stakeholders defined in 5.1.2 and the scope of application defined in 5.1.3 and shall decide the risks and opportunities that must be approached as listed below to realize the intended results of the organization.

a) Make it possible for the management of chemicals in products to achieve the intended results.
b) Enhance the desirable effects.
c) Prevent or reduce undesired effects.
d) Promote continuous improvement.

The organization shall plan their actions to address risks and opportunities according to the above.

Note:

(1) As matters that should be considered in order to clarify risk, examples include the state of the management of chemicals in products at the supplier, the products supplied from the supplier, manufacturing processes (in particular, conversion processes, manufacturing processes with a possibility of contamination, parallel production manufacturing processes where products with differing management criteria for chemicals in products are manufactured in close proximity such as at the same time in the same building), the external communication situation, and the state of understanding for related laws and regulations.

(2) To determine opportunities, it is important that top management afford the scope and possibility of improvements to reduce risk, and decide in advance at early management reviews, quality meetings, etc.

5.3.2 Objectives and planning to achieve them

The organization shall set the target for management of chemicals in products. The organization shall draw up, implement and sustain the implementation plan to achieve the target. The organization shall review the target and the implementation plan whenever needed.

When formulating a plan, the organization shall consider.

a) The integration of the actions to address risks and opportunities (5.3.1) into the management of chemicals in products, the implementation of the actions and the evaluation of their effectiveness
b) Points of improvement from performance evaluation

Note:

(1) The target shall be consistent to the management policy of chemicals in products and importantly, it should be assessable to check its achievement.

5.4 Support

5.4.1 Resources

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the management of chemicals in products.

Note:

(1) Examples of resources necessary for management of chemicals in products are as follows.

a) Persons involved in chemicals in products
Persons involved in the activities of the management of chemicals in products at each stage of design & development, purchasing, manufacturing and delivery, and persons involved in documented information management, human resource development activities, etc.

b) Infrastructure
Buildings, utilities related to buildings, equipment including hardware and software such as manufacturing equipment and inspection equipment, transportation packaging technology, information communication technology etc.

c) Knowledge
Based on internal knowledge sources such as knowledge obtained from experience, lessons learned from failure, or results of improvements, effective for the management of chemicals in

products
Based on knowledge collected from external knowledge sources such as standards, industry groups and customers

5.4.2 Competence

The organization shall conduct the following items for competence.

a) Clarify the competence required for persons involved in the management of chemicals in products at each stage of design and development, purchasing, manufacturing and delivery.
b) Ensure that the persons involved in the management of chemicals in products have competence on the basis of appropriate education/training or experience.
c) Retain documented information on the implementation of education and training.

Note:

(1) Competence is the ability to apply knowledge and skills to achieve intended results.
(2) It is important to conduct matters necessary for education & training systematically and in full to confirm that the target persons have understood.
(3) Examples of the education & training modules are contents of responsible works, management principles of chemicals in products, applicable laws, regulations and industry standards, efforts by the industrial organizations, cases of usage, misuse or contamination of declarable chemicals specified under the management criteria of chemicals in products, analytical methods, chemical substance risks etc.

5.4.3 Awareness

The organization shall ensure that persons involved in the management of chemicals in products are aware of.

a) Management Policy of Chemicals in Products
b) Objectives relating to the management of relevant chemicals in products?
c) The risks related to their own work that require attention
d) Their contribution to the effectiveness of the management of chemicals in products, including the benefits of improved performance.
e) The meaning of not conforming with the principles and action items for the management of chemicals in products.

Note:

(1) Refer to "4.2 Fundamentals of management of chemicals in products" for effects etc. caused by not conforming to the management criteria for chemicals in products.
(2) It is important to recognize that although there are various forms of systems for management of chemicals in products depending on the type of industry, type of business and business content, all departments related to design & development, purchasing, manufacturing and delivery are required to manage chemicals in products.
(3) Targets for the management of chemicals in products include suppliers, outsourcing organizations, trading companies, external warehouses, etc. who constitute the supply chain.

5.4.4 Communication

The organization shall determine the internal and external communication of the organization relevant to the management of chemicals in products, including.

a) The contents of communication
b) Implementation timing
c) Targeted persons
d) Implementation methods
e) Staff responsible

Note:

(1) It is important for communication to be carried out bidirectionally by communicating information such as meetings, document distribution etc.

5.4.4.1 Internal Communication

For the information related to the management of chemicals in products, the organization shall establish and implement procedures related to communication between the various levels and functions (departments) of the organization.

Note:

(1) The content of the information includes the management policy of chemicals in products, the management criteria for chemicals in products, objectives, implementation plans, responsibilities and authorities.
(2) It is important to confirm that the relevant departments understand the content of communications, and that they lead to necessary actions.

5.4.4.2 External communication

For information necessary for the management of chemicals in products, the organization shall establish and implement procedures related to communication with external parties.

Note:

(1) Examples of external organizations include customers, suppliers, outsourcing organizations and industry groups.
(2) The content of the information includes the management policy of chemicals in products, the management criteria for chemicals in products, information of chemicals in products, objectives, implementation plans, responsibilities and authorities. It is also important to include documented information that serves as evidence indicating the operational status of the management of chemicals in products, claims related to chemicals in products, content violation information etc.

5.4.5 Documented information

The organization shall maintain or retain the documented information recommended in the Guidelines and also the documented information defined by the organization to be necessary for the effectiveness of the management of chemicals in products.

Note:

(1) Documented information is information that the organization desires to maintain or retain and the media containing it. Documented information that is desirable to maintain is "documents" in JIS Z 7201: 2012. Documented information that is desirable to retain is that that agrees with "records." Appropriate formats, media, etc. may be selected according to the needs of the organization.
(2) Examples of documented information that should be maintained include the management policy of chemicals in products, the management manual of chemicals in products, relevant management manuals of chemicals, the standards, regulations, criteria, procedures, the systematic diagram of documentation, etc. This documented information does not need to be in manual format.
(3) Examples of documented information that should be retained include relevant information of chemicals in products, acceptance check results, delivery check results, internal audit results, etc.
(4) The organization may integrate this documented information into the documented information in other management systems implemented in the organization and manage them together.

(5) It is important that the documented information be reviewed whenever it is required, and updated versions be available for viewing whenever needed.

5.5 Operation

5.5.1 Operational planning and control

The organization shall plan, implement, manage and maintain the processes necessary to satisfy the management criteria for chemicals in products and to implement the actions determined in 5.3.1. (Refer to 5.1.4.)

The organization shall retain the level of documented information necessary to verify that the processes have been implemented in accordance with the plans.

The organization shall ensure that outsourced processes are being managed (Refer to 5.5.4).

Note:

(1) A process is a series of activities that produce planned outputs (deliverables) using the necessary resources and information as inputs. For example, regardless of the industry or business type, operations based on standards and procedures related to the management of chemicals in products such as purchasing necessary materials, manufacturing parts from purchased materials, and finishing products by combining the parts, can all be considered as processes.

5.5.2 Formulation of management criteria of chemicals in products

5.5.2.1 Customer communication

The organization shall clearly define and implement effective methods for communication with the customer for the following matters, and retain the details as documented information.

a) The acquisition of information on the laws, regulations and industry standards that the customer must comply with
b) Provision of Information on Chemicals in Products
c) Provision of information on the management of chemicals in products
d) The acquisition of feedback from the customer on products, including complaints

In case that any change is to be made to the information of chemicals in products, the organization shall notify the customer prior to such a change.

Note:

(1) An effective method of exchanging information means the organization has established an efficient system (organization, operation) which enables a quick response to enquiries or evaluations.
(2) It is important that the organization has adjusted and has an agreement in advance with suppliers and customers on the notification means and timing of notification for information of chemicals in products.
(3) The use of standardized means is recommended for transmission of information on chemicals in products.
    a) In the case of chemical products, a combination of SDS and chemSHERPA-CI etc.
    b) In the case of articles, chemSHERPA-AI, IMDS and JAMA/JAPIA unified data sheet (in the automobile field), PrimeShip-GREEN/SRM (in the ship field) etc.
(4) In case of handling confidential information, the organization shall specify how to handle such confidential information by signing the agreement with the supplier or the customer.

5.5.2.2 Defining the management criteria of chemicals in products

The organization shall determine the management criteria for chemicals in products relating to products and maintain them as documented information.

When clarifying the management criteria for chemicals in products, the organization shall define the details of items to be implemented, including.

a) The requirements of legal regulations
b) The identification of stakeholders related to the management of chemicals in products and their requirements and expectations
c) Other items considered necessary by the organization

Note:

(1) The management criteria for chemicals in products are the criteria determined by the organization in accordance with laws, regulations and the industry standards relevant to chemicals in products, and it is important to maintain and manage up-to-date information.
(2) Multiple management criteria for chemicals may be prescribed in products according to product field, destination, etc.
(3) The management criteria of chemicals in products for communication with customers include the law or the regulation to comply with, and the industry standards of the customer that are agreed upon with the customer.
(4) It is important to define the scope of application for the management criteria of chemicals in products. From a view of the organization, business operation, chemical substances, purchased products, manufacturing processes and products, the scope of application has to be defined to cover all the necessary areas. For example, the upstream organizations of the supply chain may focus on managing information on chemicals in products for delivery. Hence, the organization needs to implement management corresponding to the actual conditions of manufacturing processes.
(5) The scope of application of management criteria for chemicals in products may differ depending on the applicable laws and regulations. For example, when exporting products compared to when selling domestically.
(6) Depending on the needs of the organization, it is important to consider information to be shown to the supplier, how to obtain information of chemicals in products, data format, frequency etc.
(7) In case that the organization declares no possible inclusion in products based on scientific grounds, it is important that the evidence for this be clearly documented.
(8) In case of contract manufacturing, it is important to understand the laws and regulations that should be complied with and for the organization to clarify the management criteria of chemicals in products.

5.5.3 Management of Chemicals in Products at Design and Development

For the purpose of producing products which can fulfil the management criteria of chemicals in products in the stage of design and development, the organization shall clearly define the management criteria for chemicals in products at each stage of purchasing, manufacturing and delivery in accordance with its own products and business operation type and shall put and maintain those management criteria in a state where they can be used as documented information.

Note <Common management in design and development>

(1) “The stage of design and development” means not only works done in the design and development department, but also includes works done by relevant departments up to start of production.
(2) Not limited to design related departments, in cases such as when purchase products are selected by an organization, they will be deemed to have "design function" and shall fall under the items of these Guidelines.
(3) In consideration of the risks in the management of chemicals in products, in order for products to satisfy the management criteria for chemicals in products, it is important to specify design conditions, purchasing conditions, manufacturing processes, manufacturing conditions, delivery conditions etc. with consideration for chemicals in products for purchased products as well as chemical substances to be added, generated, or removed within the manufacturing processes.

Manufacturing conditions include incorrect use & contamination prevention and controls in the reaction process.

(4) Depending on the product to be manufactured, in the process from experiment/trial production to mass production, it is important to specify necessary matters such as the timing and scope of implementation of the acquisition and confirmation of chemicals in products for products provided from the externally and verification of the management status of chemicals in products at suppliers.

(5) For instance, the management criteria of chemicals in products for each stage which are clearly defined in design and development can be indicated in specifications, drawings, manufacturing order, and work request or in the standards.

(6) In case that the organization uses recycled material, the organization shall define the management method and operate it accordingly upon its full understanding of risks of recycled materials.

Note <Management of manufacturing chemical products at the stage of design and development>

(1) When manufacturing a single chemical substance, it is important to establish methods to predict chemical substances to be managed that may remain in the product and to monitor those chemical substances.

(2) In case the organization manufactures chemical products, the organization shall verify information on chemicals in purchased products. It is important that the organization design the manufacturing processes and products to satisfy the management criteria. If necessary, the organization shall specify the specifications of purchased products.

(3) In order to verify information of chemicals in chemical products, a commonly used mode of communication such as a combination of SDS and chemSHERPA-CI is recommended to transfer information on chemicals in products.

Note <Management of manufacturing articles using chemical products at the stage of design and development>

(1) Examples of manufacturing articles from chemical products are resin molding, surface processing such as plating, painting or printing or bonding using solder or bonding agents. For instance, in case of bonding, the organization should bear in mind that a change may occur in concentration (mass) of contained chemical substances or a chemical substance itself changing to another kind after hardening.

(2) In case of manufacturing articles from chemical products, it is important that the organization verifies information on chemicals in purchased products.

(3) In case that there is a possible change in concentration or any change in a kind of chemicals contained in products in the manufacturing process, it is crucial that the organization identifies such a change to verify whether or not the product conforms the management criteria of chemicals in products. For example, low molecular-weight compound contained in paint coat is volatilized in the baking finish process, or in the molding process of thermosetting, monomer, hardening agent or curing starter involved in curing process may change a chemical composition caused by bonding or thermosetting resin, building in or polymerization.

(4) In case that the organization which manufactures article from chemical products is unable to identify a change of chemical composition, it is essential that the organization takes a necessary action such as contacting the supplier of chemical product.

(5) In case that some chemical product is applied on manufactured articles, it is important that the organization verifies the information of chemical substances contained in chemical products. Examples of these chemical products are refrigerant, grease, lubricant or anti-rust oil.

(6) In many cases, it is operated at the same time as the process manufacturing from articles to new articles. Therefore, the organization shall focus on the management notes of designing and developing these processes.

(7) In order to verify information of chemicals in chemical products, a commonly used mode of communication such as a combination of SDS and chemSHERPA-CI is recommended to transfer information on chemicals in products.

Note <Management at the stage of design and development for manufacturing articles from article>

(1) Examples of manufacturing new articles from articles are assembling parts or mechanical processing of “metal or resin parts which are the first article converted from chemical products.”

(2) In case of manufacturing new articles form articles, the organization shall verify information of chemicals in purchased products. Furthermore, it is crucial to verify whether or not products

conform to the management criteria of management of chemicals in products.

(3) In case of using bonding agent or soldering, the process which manufactures articles using chemical products is also concurrently carried out. Therefore, the organization should pay attention to management notes on designing and developing the said process.

(4) In order to verify information of chemicals in articles, a commonly used mode of communication such as AIS, JGP file, JAMA/JAPIA standard material datasheet is recommended to transfer information on chemicals in products.

5.5.4 Management of externally provided products

5.5.4.1 Collection and Verification of Information of Chemicals in Products

After first defining the action to be taken for the acquisition of information on chemicals in products and the results of verification, the organization shall then present the management criteria related to chemicals in products in purchasing to the supplier and obtain the information on chemicals in products. The organization shall verify if the information on chemicals in products obtained satisfies the management criteria related to chemicals in products in purchasing and shall retain the result as documented information.

The acquisition and verification of information on chemicals in products in accordance with the management criteria related to chemicals in products in purchasing should be completed before the manufacturing is started.

Note:

(1) Information of chemicals in products that should be transmitted includes any inclusion of declarable chemicals that are subject to the management criteria, chemical mass, concentration or usage.

(2) The organization shall verify first if collected information of chemicals in products that should be transmitted contains all necessary data.

(3) It is crucial to identify chemical substances using identification numbers unique to individual chemical substances such as CAS numbers.

(4) Laws, regulations and the industry standard may be applied differently depending on usage of the product. Therefore, the organization shall inform the usage of products.

(5) If there is any information on chemicals in products that cannot be obtained by the deadline, it is crucial to take the required countermeasures, also considering the risks in the management of those chemicals substances in products.

5.5.4.2 Verification of the Management Status of Chemicals in Products at Supplier

The organization shall first define the action to be taken for the results of checks on the management status of chemicals in products at a supplier and then when selecting a supplier, the organization shall check that management status of chemicals in products and retain the result as documented information.

In case that the organization continues purchases with the supplier, for the purpose of fulfilling the management criteria of chemicals in products, the organization shall verify and document the supplier's management status of chemicals in products again whenever necessary.

Note:

(1) Management of chemicals in products at the supplier implies the system which appropriately manages chemicals contained in products at the respective stage of design, development, purchasing, manufacturing and delivery. In accordance with the action items provided in these Guidelines, the following items are the main elements of management.

  (a) Situation of improvements

  (b) Changes in external and internal issues related to the management of chemicals in products

  (c) Information on management performance and effectiveness with regard to chemicals in products, including regarding the following trends:

  - Relevant communication with external stakeholders
  - Level of target achievement
  - Conformance with the management criteria of chemicals in products

・Nonconformity and corrective action
・Performance evaluation results
・Supplier and external outsourcing contractor performance

(d) Suitability of resources
(e) Effectiveness of actions to address risks and opportunities
(f) Improvement planning

In case that some elements are not included, it is crucial to define the reasons and response clearly.

(2) As the method of verifying the management status of chemicals in products at the supplier, the organization can utilize the documentation or visit the supplier. It is recommended to use Check Sheet, which is an annex to the Guidelines.
(3) In case of purchasing from multiple suppliers (multi-sourcing), it is crucial to include all the suppliers.
(4) To evaluate the risk level in management of chemicals in products at the supplier, the organization can use sources such as collected information on chemicals in products, possibility of unintentional inclusion of chemicals in purchased products (the presence or absence of a conversion process or parallel production, a type of chemical product/article, etc.) the state of conformance to these Guidelines, the presence or absence of the environment or quality management system, past performances.
(5) Examples of actions upon verification result are that the organization can appoint the supplier, continue business with the supplier, request improvement to the supplier, give instructions to the supplier or cease business, etc.

5.5.4.3 Management of Chemicals in Products at Receiving

The organization shall first define the action to be taken for the results of checks on the products purchased at the time of receiving. Then, at the time of receiving, the organization shall check that the management criteria of the organization related to chemicals in products in purchasing are satisfied on the products purchased and shall retain the result as documented information.

Note:

(1) It is important to clearly define the method of verification at receiving. For example, it includes the method of judgment (to collate actual products against information, taking measurement in the organization if necessary), the method of preparing documented information on the judgment or the management method of identification.
(2) Corresponding to risks in management of chemicals in products, such as the extent of potential for the inclusion of chemicals subject to management criteria for chemicals in products, the level of management of chemicals in products at the supplier, past results, and whether or not there are recycled materials, etc., it is important to determine clearly what to be verified at receiving, the criteria, the method and frequency, etc.
(3) Outsourcing products shall also be included in product verification at receiving.
(4) In case of purchasing from multiple suppliers (multi-sourcing), it is crucial to apply the different method of verification to match risks of each supplier.
(5) In case of any risk in the management of chemicals in products, it is crucial that the organization should also include sub-materials (secondary materials) such as solder (including solder remained on products), grease, adhesives, oil, tape, cushion materials, binding materials, cushioning materials or ink (including marker pens, stamps) used for products.
(6) It is also acceptable if the organization has the ordering system only to purchase products conforming with the management criteria of chemicals in products in purchasing and verifies the order numbers or model numbers at receiving purchased products.

5.5.4.4 Verification of the Management Status of Chemicals in Products at Outsourcing

If the organization outsources some processes such as product design and development or manufacturing to another organization, then the organization shall verify the management status of chemicals in products at the outsourcing contractor to ensure that the management criteria for chemicals in products can be complied with and shall retain the result as documented information. The organization shall define the action to be taken for the verification results in advance.

Note:
(1) The outsourcing organizations shall manage themselves under their own management system of chemicals in products. It is also important that the organization should inform requirements of management to the outsourcing organizations and review their management status periodically.
(2) This action item is applicable not only outsourcing the manufacturing process, but also when the organization outsources design and development process to the outsourcing organizations.
(3) Corresponding to the outsourcing type and management risks of chemicals in products, it is important to implement effectual management. Risks are different if the organization supplies chemical products or articles to the outsourcing organization where only manufacturing process is assigned, whereas even purchasing is done in the outsourcing organizations under their own decision.
(4) In case that the organization outsources even purchasing of chemical products or articles to be used in the manufacturing process to the outsourcing organizations, it is important to define their responsibility and authority.
(5) Verification of the state of management shall also include verification of responses at times when non-conforming products occur at outsourcing organizations.
(6) As the method of verifying the management status of chemicals in products at the supplier, the organization can utilize the documentation or visit the supplier. It is recommended to use Check Sheet, which is an annex to the Guidelines.

5.5.5 Management of Chemicals in Products in Manufacturing and Storage

5.5.5.1 Management in the manufacturing process

The organization shall manage the manufacturing processes in accordance with the management criteria for chemicals in products for manufacturing processes and shall retain the results as documented information.

Note:
(1) Specifically, it is crucial that the organization should manage declarable chemicals under the management criteria of chemicals in products not to be generated or remained exceeding the level specified in the management criteria of chemicals in products at the manufacturing process by change of composition or change of concentration.
(2) It is crucial for the organization to identify the manufacturing processes required for prioritized management. For example, the organization should identify the manufacturing process which triggers composition change of chemical substances by oxidation reaction or reduction reaction, or which generates concentration change of chemicals substances by condensation or evaporation, etc., and importantly the organization shall implement the appropriate management.
(3) Caution is required because there are cases where changes of chemical composition occur in processes of change from chemical products to articles (conversion processes). For example, low molecular-weight compound contained in paint coat being volatilized in the baking finish process, in the molding process of thermosetting, monomer, hardening agent or curing starter being involved in the curing process, and bonding or building in with curing resin, or polymerization, etc., can be raised. Refer to “4.5 Conversion Process to Article” for the conversion process.
(4) It is crucial for the organization to identify the chemical substances to monitor for included quantities in each manufacturing process and to determine the methods for that monitoring (measurement method and measurement frequency, etc.) to carry out appropriate management.

5.5.5.2 Prevention of Incorrect Use and Contamination

The organization shall implement preventive measures against contamination and incorrect use of declarable chemicals under the management criteria of chemicals in products

Note:
(1) It is acceptable if preventive actions against contamination and incorrect use are designed to correspond to the management level of chemical substances which are possible to misuse or contaminate (such as forbidden to use or managing inclusions, etc.).
(2) It is crucial to prevent chemical substances used in manufacturing processes from contaminating

products that are not intended to use said products. Thorough product identification and cleaning in accordance with appropriate procedures when shifting products, or thorough cleaning of release agents and antirust preparations required only midway in processing, etc., can be raised as means for doing this.

(3) It is crucial to manage the separation of used equipment, jigs and tools, and the storage of parts, work-in-progress and finished goods (including warehouses) appropriately and to take measures to prevent contamination in accordance with the potential for contamination, even with packaging materials and protective materials that do not go into products.

(4) As a specific method to implement the management of chemicals in products efficiently and effectively, there is the method of separating the process that requires prioritized management from other processes, with consideration given to risk in the management of chemicals in products. The process which requires prioritized management includes parallel production. Effective management is made possible by managing this separately from other processes. Refer to "Annex B： Parallel Production."

5.5.5.3 Identification and traceability

The organization shall assure traceability of the information of chemicals in products by appropriate manners in order to grasp, utilize, disclose and transfer the information of chemicals in products swiftly.

The organization shall define, save and implement the management method for chemicals in products information related to products.

Note:

(1) Traceability is to associate the documented information on the preferability of retaining the information on components and parts of each product, when and where the product was manufactured, and information of chemicals contained in components or manufactured products, etc., and capturing that information corresponding to the management risk of chemicals in products, for the purpose of identifying the extent of nonconformance or providing the information at the time of change. Furthermore, it is also to establish the system to utilize, release and transfer such information.

5.5.6 Change management

The organization shall extract changeable elements which may affect declarable chemicals under the management criteria of chemicals in products. When any change arises, before the actual change takes place, the organization shall effectually confirm the change to be made to the chemicals in products and conduct a review based on the management criteria of chemicals in products.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Note:

(1) The elements of changes could include changes or additions of suppliers, changes in purchased products or changes of manufacturing process, etc.

(2) Changes in the supply chain related to suppliers and outsourcing contractors are also subject to management, not just changes within the organization, and it is crucial to subject changes at suppliers and outsourcing contractors to management too. It is essential to define the communication flow with the supplier, the outsourcing organizations and the customers.

(3) It is important that the organization collects the supplier's change information prior to any change taken place. It is also important that the organization notifies the suppliers (including 2nd or 3rd tier suppliers) about the procedures of change management.

(4) It is important to verify conformance to the management criteria of chemicals in products prior to any change taken place.

(5) It is important to notify the customers of the change information prior to any change taken place. In case that any change is occurred to chemicals in products, the organization shall provide updated information on chemicals in products swiftly. It is also important that the organization provides lot information or identification information to the customers.

(7) Generally, the change management includes the four production elements of Man, Machine, Material and Method (4M). In addition, the measuring method (Measurement) should also be taken

into consideration.
(8) In cases where there will be changes to chemicals contained in products which are delivered to unspecified numbers of customers (such as catalogue products, commercial products), it may be difficult to inform all customers of the changes in advance so it is crucial to enable identification.

5.5.7 Delivery of products

Before the organization delivers products, the organization shall verify that the products satisfy the management criteria of chemicals in products for delivery.

The organization shall retain documented information on the delivery of products. This information shall include the following.

a) Proof of conformance with the management criteria of chemicals in products

b) Traceability to the person(s) authorizing the delivery

The organization shall also manage product warehouses to prevent incorrect shipment and contamination.

The organization shall consider matters such as the laws, regulations and industry criteria covered by the management criteria for chemicals in products, any nonconformance and the feedback from customers and shall also decide and implement the action to be taken after delivery for the products supplied.

Note:

(1) In receiving or in the manufacturing process, it is crucial that the organization verifies again that all check items stipulated in advance have been implemented completely.
(2) The following are examples of verification items at delivery.
   a) Purchased products are verified at receiving before used for manufacturing.
   b) Products are manufactured in accordance with the management criteria of chemicals in products at the respective stage.
   c) In case of any change, the history of change is recorded and stored.
   d) When nonconformance is found, a proper action is taken to tackle nonconformance.
   e) When necessary, sampling is done for verification.
(3) The following are the examples of verification method.
   a) With an identification tag, the management status can be captured in the manufacturing process.
   b) The management data can be captured in the manufacturing process by the production management system.

5.5.8 Response to occurrence of nonconformity

The organization shall decide and document the methods to be used when nonconformity in chemicals in products occurs, to quickly contact persons within the organization, suppliers, outsourcing contractors and customers and to take temporary corrective action. After the temporary measure is taken, the organization shall investigate and identify the cause and determine and implement the necessary countermeasures to prevent recurrence. The organization shall take preventive measures to avoid any occurrence of nonconformity. The organization shall retain documented information on the action when a nonconforming product occurs.

Note:

(1) It is important that the organization should determine the definition of nonconformity of chemicals in products and specify the level of nonconformity and the response corresponding to the level.
(2) The examples of temporary measures are to identify an affected area (to identify the nonconforming lot, nonconforming equipment, etc.), and to prevent expansion of the nonconformity (to stop shipment, to stop production, etc.).
(3) As for contacting in-house, in some cases, contacting top managers is crucial.
(4) It is important to specify that the first report shall be made immediately to inform the occurrence of nonconformance externally to the suppliers, the outsourcing organizations and the customers. It is also important that the organization sets the notification period prior to any nonconformance or requests to report immediately upon occurrence of nonconformance.
(5) After a temporary is measure is taken, the organization shall determine and implement a necessary

measure, and importantly prevent recurrence of the problem. Recurrence-preventive measures should be implemented not only in its own organization, but also implemented widely at relevant organizations (such as in group organizations or affiliates, etc.) when necessary.

(6) It is advisable that the organization implements preventive measures to avoid occurrence of nonconformance. For example, taking measurement of lead concentration in solder bath regularly can be implanted as management of manufacturing process.

5.6 Performance evaluation and improvement

The organization shall evaluate the following items at predetermined intervals. The organization shall implement corrective action for matters which require correction. The organization shall retain the results of evaluations and corrective action as documented information and shall report the results to top management. The top management shall review those results of evaluations and corrective action.

a) Situation of improvements
b) Changes in external and internal issues related to the management of chemicals in products
c) Information on management performance and effectiveness with regard to chemicals in products, including regarding the following trends:
   1) Relevant communication with external stakeholders
   2) Level of target achievement
   3) Conformance with the management criteria of chemicals in products
   4) Nonconformity and corrective action
   5) Performance evaluation results
   6) Supplier and external outsourcing contractor performance
d) Suitability of resources
e) Effectiveness of actions to address risks and opportunities
f) Improvement planning

Note:

(1) It is crucial that the organization monitors and evaluates the observance of the criteria for the management of chemicals in products, and evaluates the effectiveness of the performance of the management of chemicals in products.

(2) It is crucial that top management reviews the documented information, and plans and implements improvements in the organization and its operation.

6. Evaluation based on the Guidelines for the Management of Chemicals in Products and Self-Declaration of Conformance

6.1 Evaluation of the management of chemicals in products

In order for the organization involved in the supply chain to implement the management of chemicals in products and improve the management level of the supply chain overall, it is important that the state of management is evaluated appropriately, that the necessary improvements are made based on the results of evaluation and that the management system is sustained.

These Guidelines contain “Annex E: Check Sheet” in order to evaluate the management system of chemicals in products. By utilizing this Check Sheet, the organization is able to make a comprehensive evaluation of compliance with the applicable action items and the management system overall efficiently and objectively.

6.2 Check Sheet

In the Check Sheet, which is an Annex of these Guidelines, there are a few questions on each action item presented in “5. Action items for the management of chemicals in products” from the viewpoints of the rules (fundamentals and procedures, etc.) established by the organization and operations based on those rules. Therefore, The Check Sheet enables the conformance evaluation.

As shown in Table 6-1, the questions on the Check Sheet are classified into broad categories (common management, process management) and detailed categories (verification of criteria existence, verification of implementation, review checks, verification of notification, verification of documentation and verification of recording) based on their content.

In addition, they are also classified into the two levels of “basic level” and “advanced level” depending on the level of the question. The questions of “Basic level” are based on content in compliance with the guidelines stated in JIS Z 7201:2017 “The Management of Chemical Substances in Products – Principles and Guidelines.” These questions are items to be evaluated for self-declaration of conformance.

Table 6-1 Classification of Questions on the Check Sheet

Classification	Description
Basic level	- Questions in compliance with the guidelines of JIS Z 7201:2017 “The Management of Chemical Substances in Products – Principles and Guidelines” - Conformance is required for the self-declaration of conformance related to the management of chemicals in products based on these guidelines - Basic management requirements under the management system of chemical substance control mechanism - Milestones targeting the management system to be established and sustained for managing chemicals in products reliably and efficiently (Advanced level)
Advanced level	- Questions specifying an appeal for implementation efforts by the supplier or expected customer requests - A group of requirements under the management system to manage chemicals in products reliably and efficiently

6.3 Evaluation of conformance with action items and overall evaluation of the management system

(1) Evaluation of conformance with each action item

In order to evaluate the systematic management system for the management of chemicals stated in these Guidelines, each action item needs to be evaluated for conformance and a judgment made comprehensively.

Evaluation of conformance with each action item shall be carried out by using the Check Sheet and evaluating conformance with the question or multiple questions provided for each action item that requires verification. Evaluation is carried out using the three levels of conformance, partial conformance and nonconformance in accordance with the conformance judgment criteria shown in Table 6-2. More specific conformance judgment criteria are stated for each question in the columns “Conformance judgment criteria,” “Sample answer” and “Points to note in management” on the Check Sheet, and evaluation of conformance with each question shall be carried out in accordance with those judgment criteria. Questions which are not applicable to the organization for managing chemicals in products are exempted from implementation or evaluation and should be handled as “non-applicable.”

Conformance with an action item is judged by conformance with all of the basic level questions provided for the action item in question.

Table 6-2 Judgment Criteria for Conformance for Action Items

Judgment	Criteria
conformity	- In order to satisfy the action items, it is necessary to have rules established by the organization (fundamentals and procedures, etc.) and operations based on those rules. Each question to the action item is designed basically from the perspective of rules and operation. As a reply to the question, if operation is properly practiced in accordance with rules, it is judged as “conformance.” For operation based on rules, it is necessary to verify the management status objectively.
Partial conformance	- Evaluate as “partial conformance” when management is practically carried out to satisfy contents of the questions, however rules or operation is partially insufficient. The other cases for partial conformance include: operation is not completely followed based on rules, there is some delay in operation although there are rules to satisfy the action items, or operation fulfills the action items, however rules are not established sufficiently or rules are not up to date. - In any case, insufficient operation or incomplete rules need to be improved to achieve the level of conformance. As with the case of conformance, it is necessary to verify the management status objectively. Furthermore, in case of “partial conformance,” the contents of nonconformance shall be identified and its improvement plan shall be provided.
nonconformity	- Evaluate as “nonconformance,” in case that the organization has not established rules which correspond to the question and/or no operation is carried out to satisfy the questions.
Non applicable	- Evaluate as “non-applicable” in case that the action item is not subject to management of chemicals in products in the organization. - It is necessary to show the grounds for judging non-applicable. - Caution is required over the potential for the organization to bear a significant risk if a non-applicable judgment is made mistakenly and action items not implemented, and also for it to be judged externally that there are problems in the organization’s awareness of the management of chemicals in products.

In cases where the management system of chemical substance in products is developed and implemented in accordance with other criteria or other guidelines that are equivalent or higher level compared to these Guidelines, the organization shall evaluate conformance by judging whether or not each action item practically fulfills questions.

(2) Total evaluation of the management system of chemicals in products

Comprehensive evaluation of all the action items, in other words, the overall management system of chemicals in products can evaluate from total scores of each action item. Judging criteria of comprehensive evaluation shall be set by each user. In case that the organization is going to announce a self-declaration of conformance for the management system of chemicals in products, the following section shows the judging criteria of comprehensive evaluation.

6.4 Self-Declaration of Conformance on the Management System of Chemicals in Products

(1) Objective of self-declaration of conformance

Self-declaration of conformance is to perform self-evaluation on the management system of chemicals in products, to understand its weakness, to make improvements and to promote communication of highly reliable data to the supply chain. Furthermore, self-declaration of conformance enables the organization to appeal its initiative of managing chemicals in products by announcing it to the community.

(2) Comprehensive judging criteria for self-declaration of conformance

Self-declaration of conformance on the management system of chemicals in products is to issue a declaration that the organization has developed and implemented the management system of chemicals in products in accordance with these Guidelines in the organization.

Comprehensive judgment for self-declaration of conformance is based on the judgment result for each action item. If the judgment result satisfies the criteria shown in Table 6-3, it is evaluated as conformance and the organization can issue a self-declaration of conformance for the management system of chemicals in products.

Table 6-3 Comprehensive Judging Criteria for Self-Declaration of Conformance on the Management of Chemicals in Products

Comprehensive judging criteria	- Cases where all evaluations of applicable questions among the basic questions provided for each “action item” are “Conformance”

(3) Responsibilities associated with self-declaration of conformance

When issuing a self-declaration of conformance, Rules 1) - 5) below must be observed.

1) The organization shall be responsible for the contents of self-declaration of conformance.
2) Documented records of verification of conformance shall be stored. The retention period shall be determined by each organization based on its own judgment.
3) The organization shall prepare the self-declaration of conformance where the contents of the self-declaration are described. Refer to “Annex F: Self-declaration of conformance” for a sample of self-declaration of conformance.
4) Self-declaration of conformance shall be disclosed whenever there is a request either from in-house or externally.
5) The contents of self-declaration of conformance shall be continuously operated and the organization shall verify conformance with the Guidelines periodically.

(4) Disclosure of documented information used in verification

The self-declaration of conformance is conducted under the organization’s responsibility. The purchasers may request from suppliers the disclosure of the documented information used in verification for self-declaration of conformance. In such cases, it is desirable that the documented information used in verification be disclosed after mutual consultation.

Annex A: JIS Z 7201, Comparison with the Quality and Environmental Management Systems

The Table below shows the action items of these Guidelines and technical correspondence with JIS Z 7201:2017 and quality and environmental management systems. The objective of this comparison is to provide reference information to the organization which already operates either one or both standards of the quality management system and the environmental management system, while such an organization newly develops systems for the management of chemicals in products or verifies the effectiveness of the management system.

In case that the contents of the action items match to a certain extent, the corresponding relationships of the items are shown in the comparison table. However, it should be noted that there are other comparatively weak correlations.

Table A-1 Action Items of these Guidelines, JIS Z 7201:2017 Guidelines Comparisons with ISO 9001:2015 and ISO 14001:2015 requirements

Guidelines for the Management of Chemicals in Product Ed. 4.0		JIS Z 7201:2017		ISO 9001:2015 (JIS Q 9001:2015)		ISO 14001:2015 (JIS Q 14001:2015)	
5	Action Items for Management of Chemicals in Products	5	Guidelines for the management of chemicals in products (title only)	-	-	-	-
5.1	State of organization (title only)	5.1	State of organization (title only)	4	State of organization (title only)	4	State of organization (title only)
5.1.1	Understanding the organization and its context	5.1.1	Understanding the organization and its context	4.1	Understanding the organization and its context	4.1	Understanding the organization and its context
5.1.2	Understanding the needs and expectations of stakeholders	5.1.2	Understanding the needs and expectations of stakeholders	4.2	Understanding the needs and expectations of stakeholders	4.2	Understanding the needs and expectations of stakeholders
5.1.3	Determining the scope of application of management of chemicals in products	5.1.3	Determining the scope of application of management of chemicals in products	4.3	Determining the scope of application of quality management systems	4.3	Determining the scope of application of environmental management systems
5.1.4	Implementation of the management of chemicals in products	5.1.4	Implementation of the management of chemicals in products	4.4	Quality management systems and processes	4.4	Environmental management systems
				4.4.1	(No title)		
				4.4.2	(No title)		
5.2	Leadership (title only)	5.2	Leadership (title only)	5	Leadership (title only)	5	Leadership (title only)
5.2.1	Leadership and commitment	5.2.1	Leadership and commitment	5.1	Leadership and commitment	5.1	Leadership and commitment
				5.1.1	General		
-	-	-	-	5.1.2	Customer focus	-	-
5.2.2	Policy	5.2.2	Policy	5.2	Policy	5.2	Environmental policy
				5.2.1	Establishment of quality policy		
				5.2.2	Transmission of quality policy		

Guidelines for the Management of Chemicals in Product Ed. 4.0		JIS Z 7201:2017		ISO 9001:2015 (JIS Q 9001:2015)		ISO 14001:2015 (JIS Q 14001:2015)	
5.2.3	Roles, responsibility and authority of an organization	5.2.3	Roles, responsibility and authority of an organization	5.3	Roles, responsibility and authority of an organization	5.3	Roles, responsibility and authority of an organization
5.3	Planning (title only)	5.3	Planning (title only)	6	Planning (title only)	6	Planning (title only)
5.3.1	Actions to address risks and opportunities	5.3.1	Actions to address risks and opportunities	6.1	Actions to address risks and opportunities	6.1	Actions to address risks and opportunities
				6.1.1	(No title)	6.1.1	General
				6.1.2	(No title)	6.1.2	Environmental aspects
						6.1.3	Compliance obligation
						6.1.4	Planning of actions
5.3.2	Objectives and planning to achieve them	5.3.2	Objectives and planning to achieve them	6.2	Quality objectives and planning to achieve them	6.2	Environmental objectives and planning to achieve them
				6.2.1	(No title)	6.2.1	Environmental objectives
				6.2.2	(No title)	6.2.2	Planning of actions to achieve environmental objectives
				6.3	Change planning	-	-
5.4	Support (title only)	5.4	Support (title only)	7	Support (title only)	7	Support (title only)
5.4.1	Resources	5.4.1	Resources	7.1	Resources (title only)	7.1	Resources
				7.1.1	General		
				7.1.2	People		
				7.1.3	Infrastructure		
				7.1.4	Environment related to process operation		
				7.1.5	Resources for monitoring and measurement		
				7.1.5.1	General		
				7.1.5.2	Traceability of measurement		
				7.1.6	Knowledge of the organization		
5.4.2	Competence	5.4.2	Competence	7.2	Competence	7.2	Competence
5.4.3	Awareness	5.4.3	Awareness	7.3	Awareness	7.3	Awareness
5.4.4	Communication	5.4.4	Communication	7.4	Communication	7.4	Communication (title only)
						7.4.1	General
5.4.4.1	Internal communication	5.4.4.1	Internal communication			7.4.2	Internal communication
5.4.4.2	External communication	5.4.4.2	External communication			7.4.3	External communication
5.4.5	Documented information	5.4.5	Documented information	7.5	Documented information (title only)	7.5	Documented information (title only)
				7.5.1	General	7.5.1	General

Guidelines for the Management of Chemicals in Product Ed. 4.0		JIS Z 7201:2017		ISO 9001:2015 (JIS Q 9001:2015)		ISO 14001:2015 (JIS Q 14001:2015)	
				7.5.2	Production and updates	7.5.2	Production and updates
				7.5.3	Management of documented information (title only)	7.5.3	Management of documented information
				7.5.3.1	(No title)		
				7.5.3.2	(No title)		
5.5	Operation (title only)	5.5	Operation (title only)	8	Operation (title only)	8	Operation (title only)
5.5.1	Operational planning and control	5.5.1	Operational planning and control	8.1	Operational planning and control	8.1	Operational planning and control
5.5.2	Formulation of management criteria of chemicals in products	5.5.2	Formulation of management criteria of chemicals in products	8.2	Requirements for products and services	8.2	Emergency preparedness and response
5.5.2.1	Customer communication	5.5.2.1	Customer communication	8.2.1	Customer communication		
5.5.2.2	Defining the management criteria of chemicals in products	5.5.2.2	Defining the management criteria of chemicals in products	8.2.2	Clarification of requirements for products and services		
-	-	-	-	8.2.3	Review of requirements for products and services		
				8.2.3.1	(No title)		
				8.2.3.2	(No title)		
-	-	-	-	8.2.4	Changes to requirements for products and services		
5.5.3	Management of Chemicals in Products at Design and Development	5.5.3	Management of Chemicals in Products at Design and Development	8.3	Design and development of products and services		
				8.3.1	General		
				8.3.2	Design and development planning		
				8.3.3	Inputs to design and development		
				8.3.4	Design and development management		
				8.3.5	Outputs from design and development		
				8.3.6	Design and development changes		
5.5.4	Management of externally provided products (title only)	5.5.4	Management of externally provided products (title only)	8.4 8.4.1 8.4.2 8.4.3	General management of externally provided		

Guidelines for the Management of Chemicals in Product Ed. 4.0		JIS Z 7201:2017		ISO 9001:2015 (JIS Q 9001:2015)		ISO 14001:2015 (JIS Q 14001:2015)	
5.5.4.1	Collection and Verification of Information of Chemicals in Products	5.5.4.1	Collection and Verification of Information of Chemicals in Products		processes, products and services Management methods and degrees Information on external suppliers		
5.5.4.2	Verification of the Management Status of Chemicals in Products at Supplier	5.5.4.2	Verification of the Management Status of Chemicals in Products at Supplier				
5.5.4.3	Management of Chemicals in Products at Receiving	5.5.4.3	Management of Chemicals in Products at Receiving				
5.5.4.4	Verification of the Management Status of Chemicals in Products at Outsourcing	5.5.4.4	Verification of the Management Status of Chemicals in Products at Outsourcing				
5.5.5	Management of Chemicals in Products in Manufacturing and Storage	5.5.5	Management of Chemicals in Products in Manufacturing and Storage	8.5	Production and service operation		
5.5.5.1	Management in the manufacturing process	5.5.5.1	Management in the manufacturing process	8.5.1	Control of production and service provision		
5.5.5.2	Prevention of Incorrect Use and Contamination	5.5.5.2	Prevention of Incorrect Use and Contamination	-	-		
5.5.5.3	Identification and traceability	5.5.5.3	Identification and traceability	8.5.2	Identification and traceability		
-	-	-	-	8.5.3	Property of customers and external suppliers		
-	-	-	-	8.5.4	Maintenance		
5.5.6	Change management	5.5.6	Change management	8.5.6	Change management		
5.5.7	Delivery of products	5.5.7	Delivery of products	8.6	Release of products and services		
				8.5.5	Activities after delivery		
5.5.8	Response to Occurrence of Nonconformity	5.5.8	Response to Occurrence of Nonconformity	8.7	Management of nonconforming output		
				8.7.1	(No title)		
				8.7.2	(No title)		
5.6	Performance evaluation and improvement	5.6	Performance evaluation and improvement	9	Performance evaluation (title only)	9	Performance evaluation (title only)
				9.1	Monitoring, measurement, analysis and evaluation (title only)	9.1	Monitoring, measurement, analysis and evaluation (title only)
				9.1.1	General	9.1.1	General

Guidelines for the Management of Chemicals in Product Ed. 4.0		JIS Z 7201:2017		ISO 9001:2015 (JIS Q 9001:2015)		ISO 14001:2015 (JIS Q 14001:2015)	
				-	-	9.1.2	Evaluation of compliance
				9.1.2	Customer satisfaction	-	-
				9.1.3	Analysis and evaluation	-	-
				9.2	Internal audit (title only)	9.2	Internal audit (title only)
				9.2.1	(No title)	9.2.1	General
				9.2.2	(No title)	9.2.2	Internal audit program
				9.3	Management review (title only)	9.3	Management review
				9.3.1	General		
				9.3.2	Inputs to management reviews		
				9.3.3	Outputs from management reviews		
	(“Improvement” is included in 5.6)		(“Improvement” is included in 5.6)	10	Improvement (title only)	10	Improvement (title only)
				10.1	General	10.1	General
				10.2	Nonconformity and corrective action	10.2	Nonconformity and corrective action
				10.2.1	(No title)		
				10.2.2	(No title)		
				10.3	Continuous improvement	10.3	Continuous improvement

Annex B : Parallel Production

During any process of receiving check - storage warehouse - manufacturing process - warehouse storage of WIP/end products - delivery, production which uses chemical products and parts containing restricted chemical substances under laws and regulations is carried out, while products which are restricted to contain the said chemical substances are also manufactured concurrently in the same factory building. This is called parallel production and it is important to implement preventive measure against contamination or incorrect use. The following are the examples of parallel production and non-parallel production.

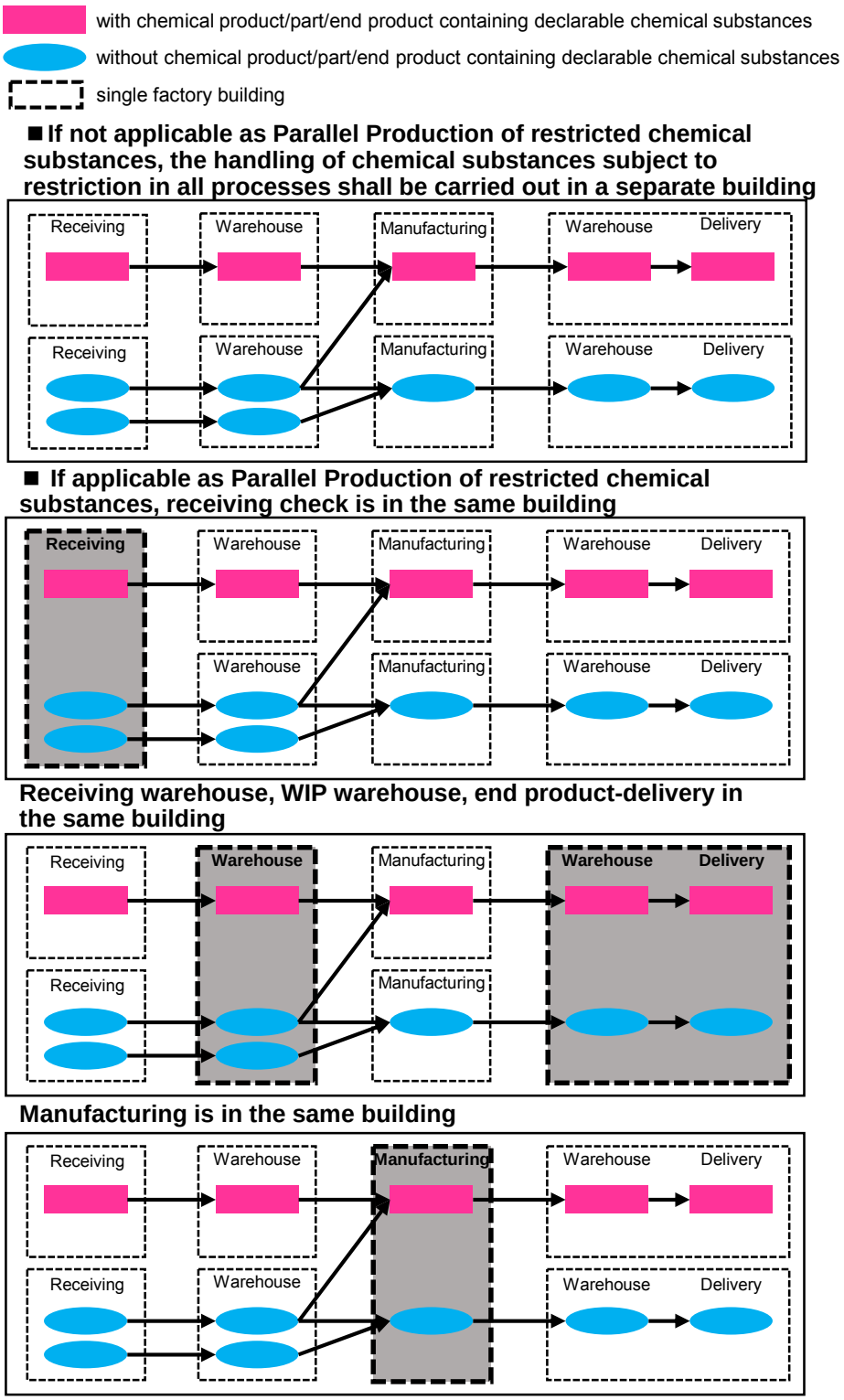

Fig B-1 Image of parallel production

Annex C：Action Item corresponding to Seven Management Frameworks for Chemicals in Products

Table C-1 shows the relevant clause numbers of the guidelines, etc., corresponding to the seven management frameworks of the management of chemicals in products. The actions items of these Guidelines are stated in the form of PDCA for the purpose of providing them as reference information when the organization verifies requirements for management of chemicals in products which are required under each management framework.

Table C-1 Basic way of thinking, action items and annexes related to the seven management frameworks of the management of chemicals in products

Management Framework		Corresponding action items and notes, etc.	
I	Purchasing chemical product	5.5.3	Management of chemicals in products at design and development (Note: Common management in design and development, management in the manufacture of chemical products, management in the design and development stage of the manufacturing of articles that use chemical products)
		5.5.4.1	Collection and Verification of Information of Chemicals in Products
		5.5.4.2	Verification of the Management Status of Chemicals in Products at Supplier
		5.5.4.3	Management of Chemicals in Products at Receiving
II	Manufacturing chemical product	5.5.3	Management of chemicals in products at design and development (Note: Common management in design and development, management in the manufacture of chemical products, management in the design and development stage of the manufacturing of articles that use chemical products)
		5.5.5.1	Management in the manufacturing process
		5.5.5.2	Prevention of Incorrect Use and Contamination
		4.5	Conversion Process to Article
III	Delivery of chemical product	5.5.3	Management of chemicals in products at design and development (Notes related to common management in design and development, management in the manufacture of chemical products, management in the design and development stage of the manufacturing of articles that use chemical products)
		5.5.7	Delivery of products
IV	Purchasing article	5.5.3	Management of chemicals in products at design and development (Note: Common management in design and development, management in the design and development stage of the manufacturing of articles that use chemical products)
		5.5.4.1	Collection and Verification of Information of Chemicals in Products
		5.5.4.2	Verification of the Management Status of Chemicals in Products at Supplier
		5.5.4.3	Management of Chemicals in Products at Receiving
V	Manufacturing article	5.5.3	Management of chemicals in products at design and development (Note: Common management in design and development, management in the design and development stage of the manufacturing of articles that use chemical products)

Management Framework		Corresponding action items and notes, etc.	
		5.5.5.1	Management in the manufacturing process
		5.5.5.2	Prevention of Incorrect Use and Contamination
VI	Delivery of article	5.5.3	Management of chemicals in products at design and development (Note: Common management in design and development, management in the design and development stage of the manufacturing of articles that use chemical products)
		5.5.7	Delivery of products
VII	Common management	5.1	Context of the organization
		5.2	Leadership
		5.3	Plan
		5.4	Support
		5.5.1	Operational planning and control
		5.5.2	Formulation of management criteria of chemicals in products
		5.5.4.4	Verification of the Management Status of Chemicals in Products at Outsourcing
		5.5.5.3	Identification and traceability
		5.5.6	Change management
		5.5.8	Response to Occurrence of Nonconformity
		5.6	Performance evaluation and improvement
		Annex B	Parallel Production

Annex D： List of Action Items

The list of action items shown in “5. Action Items for Management of Chemicals in Products” is shown below.

Action Items	Check Sheet questions
5.1 Context of the organization	(title only)
5.1.1 Understanding the organization and its context	Reference
The organization shall clarify external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its management of chemicals in products.	
5.1.2 Understanding the needs and expectations of stakeholders	Reference
The organization shall clarify the following items to understand the needs and expectations of stakeholders. a) The stakeholders closely related to the management of chemicals in products b) The requirements of those stakeholders that are closely related to the management of chemicals in products	
5.1.3 Determining the Scope of Application of Management of Chemicals in Products	1
The organization shall determine the appropriate scope of application of management of chemicals in products. When determining this scope, the organization shall consider: a) The external and internal issues for the organization defined in 5.1.1 b) The requirements of stakeholders defined in 5.1.2 c) The relationship between the organization and chemical substances d) The externally provided products handled by the organization and the products delivered to external parties The scope of application of management of chemicals in products shall be put in a state that can be used as documented information.	
5.1.4 Implementation of the Management of Chemicals in Products	Reference
The organization shall establish, implement, sustain and continuously improve the management system for chemicals in products in accordance with the basic thinking and action items stated in these Guidelines. For the purpose of producing products which can fulfil the management criteria of chemicals in products, the management of chemicals in products shall be carried out according to the type of business operations of the organization at each stage of design and development, purchasing, manufacturing and delivery.	
5.2 Leadership	(title only)
5.2.1 Leadership and commitment	Reference
Top management shall demonstrate leadership and commitment with respect to the management of chemicals in products by. a) Taking accountability for the effectiveness of the management of chemicals in products. b) Positioning the management of chemicals in products as an activity of the organization. c) Making the necessary resources available for use (Refer to 5.4.1). d) Ensuring compliance with the management criteria for chemicals in products.	
5.2.2 Policy	1
The top management shall establish the management policy of chemicals in products for the organization and shall formulate, implement and sustain plans based on that policy. Furthermore, the top management shall state that it will appropriately implement the management of chemicals in products.	
5.2.3 Roles, responsibility and authority of an organization	1

Action Items	Check Sheet questions
In order to implement effective management of chemicals in products, the top management shall define the responsibilities and authorities for the relevant roles and communicate this within the organization.	
5.3 Plan	(title only)
5.3.1 Actions to address risks and opportunities	Reference
When formulating a plan for the management of chemicals in products, the organization shall consider the external and internal issues for the organization defined in 5.1.1, the requirements of stakeholders defined in 5.1.2 and the scope of application defined in 5.1.3 and shall decide the risks and opportunities that must be approached as listed below to realize the intended results of the organization. a) Make it possible for the management of chemicals in products to achieve the intended results. b) Enhance the desirable effects. c) Prevent or reduce the undesired effects. d) Promote continuous improvement. The organization shall plan their actions to address risks and opportunities according to the above.	
5.3.2 Objectives and planning to achieve them	3
The organization shall set the target for management of chemicals in products. The organization shall draw up, implement and sustain the plan to achieve the target. The organization shall review the target and the implementation plan whenever needed. When formulating a plan, the organization shall consider: a) The integration of the actions to address risks and opportunities (5.3.1) into the management of chemicals in products, the implementation of the actions and the evaluation of their effectiveness b) Points of improvement from performance evaluation	
5.4 Support	(title only)
5.4.1 Resources	Reference
The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the management of chemicals in products.	
5.4.2 Competence	1
The organization shall conduct the following items for competence. a) Clarify the competence required for persons involved in the management of chemicals in products at each stage of design and development, purchasing, manufacturing and delivery. b) Ensure that the persons involved in the management of chemicals in products have competence on the basis of appropriate education/training or experience. c) Retain documented information on the implementation of education and training.	
5.4.3 Awareness	Reference
The organization shall ensure that persons involved in the management of chemicals in products are aware of. a) Management Policy of Chemicals in Products b) Objectives relating to the management of relevant chemicals in products? c) The risks related to their own work that require attention d) Their contribution to the effectiveness of the management of chemicals in products, including the benefits of improved performance. e) The meaning of not conforming with the principles and action items for the management of chemicals in products.	
5.4.4 Communication	Reference

Action Items	Check Sheet questions
The organization shall determine the internal and external communication of the organization relevant to the management of chemicals in products, including. a) The contents of communication b) Implementation timing c) Targeted persons d) Implementation methods e) Staff responsible	
5.4.4.1 Internal communication	Reference
For the information related to the management of chemicals in products, the organization shall establish and implement procedures related to communication between the various levels and functions (departments) of the organization.	
5.4.4.2 External communication	Reference
For information necessary for the management of chemicals in products, the organization shall establish and implement procedures related to communication with external parties.	
5.4.5 Documented information	2
The organization shall maintain or retain the documented information recommended in the Guidelines and also the documented information defined by the organization to be necessary for the effectiveness of the management of chemicals in products.	
5.5 Operation	(title only)
5.5.1 Operational planning and control	Reference
The organization shall plan, implement, manage and maintain the processes necessary to satisfy the management criteria for chemicals in products and to implement the actions determined in 5.3.1. (Refer to 5.1.4.) The organization shall retain the level of documented information necessary to verify that the processes have been implemented in accordance with the plans. The organization shall ensure that outsourced processes are being managed (Refer to 5.5.4).	
5.5.2 Formulation of management criteria of chemicals in products	(title only)
5.5.2.1 Customer communication	2
The organization shall clearly define and implement effective methods for communication with the customer for the following matters, and retain the details as documented information. a) The acquisition of information on the laws, regulations and industry standards that the customer must comply with b) Provision of Information on Chemicals in Products c) Provision of information on the management of chemicals in products d) The acquisition of feedback from the customer on products, including complaints In case that any change is to be made to the information of chemicals in products, the organization shall notify the customer prior to such a change.	
5.5.2.2 Defining the management criteria of chemicals in products	1
The organization shall determine the management criteria for chemicals in products relating to products and maintain them as documented information. When clarifying the management criteria for chemicals in products, the organization shall define the details of items to be implemented, including. a) The requirements of legal regulations b) The identification of stakeholders related to the management of chemicals in products and their requirements and expectations c) Other items considered necessary by the organization	
5.5.3 Management of Chemicals in Products at Design and Development	1
For the purpose of producing products which can fulfil the criteria for chemicals in products in the stage of design and development, the organization shall clearly define the management	

Action Items	Check Sheet questions
criteria for chemicals in products at each stage of purchasing, manufacturing and delivery in accordance with its own products and business operation type and shall put and maintain those management criteria in a state where they can be used as documented information.	
5.5.4 Management of externally provided products	(title only)
5.5.4.1 Collection and Verification of Information of Chemicals in Products	7
After first defining the action to be taken for the acquisition of information on chemicals in products and the results of verification, the organization shall then present the management criteria related to chemicals in products in purchasing to the supplier and obtain the information on chemicals in products. The organization shall verify if the information on chemicals in products obtained satisfies the management criteria related to chemicals in products in purchasing and shall retain the result as documented information. The acquisition and verification of information on chemicals in products in accordance with the management criteria related to chemicals in products in purchasing should be completed before the manufacturing is started.	
5.5.4.2 Verification of the Management Status of Chemicals in Products at Supplier	10
The organization shall first define the action to be taken for the results of checks on the management status of chemicals in products at a supplier and then when selecting a supplier, the organization shall check that management status of chemicals in products and retain the result as documented information. In case that the organization continues purchases with the supplier, for the purpose of fulfilling the management criteria of chemicals in products, the organization shall verify and document the supplier's management status of chemicals in products again whenever necessary.	
5.5.4.3 Management of Chemicals in Products at Receiving	2
The organization shall first define the action to be taken for the results of checks on the products purchased at the time of receiving. Then, at the time of receiving, the organization shall check that the management criteria of the organization related to chemicals in products in purchasing are satisfied on the products purchased and shall retain the result as documented information.	
5.5.4.4 Verification of the Management Status of Chemicals in Products at Outsourcing	3
If the organization outsources some processes such as product design and development or manufacturing to another organization, then the organization shall verify the management status of chemicals in products at the outsourcing contractor to ensure that the management criteria for chemicals in products can be complied with and shall retain the result as documented information. The organization shall define the action to be taken for the verification results in advance.	
5.5.5 Management of Chemicals in Products in Manufacturing and Storage	(title only)
5.5.5.1 Management in the manufacturing process	4
The organization shall manage the manufacturing processes in accordance with the management criteria for chemicals in products for manufacturing processes and shall retain the results as documented information.	
5.5.5.2 Prevention of Incorrect Use and Contamination	6
The organization shall implement preventive measures against contamination and incorrect use of declarable chemicals under the management criteria of chemicals in products.	
5.5.5.3 Identification and traceability	1
The organization shall assure traceability of the information of chemicals in products by appropriate manners in order to grasp, utilize, disclose and transfer the information of chemicals in products swiftly. The organization shall define, save and implement the management method for chemicals in products information related to products.	
5.5.6 Change management	4

Action Items	Check Sheet questions
The organization shall extract changeable elements which may affect declarable chemicals under the management criteria of chemicals in products. When any change arises, before the actual change takes place, the organization shall effectually confirm the change to be made to the chemicals in products and conduct a review based on the management criteria of chemicals in products. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.	
5.5.7 Delivery of products	1
Before the organization delivers products, the organization shall verify that the products satisfy the management criteria of chemicals in products for delivery. The organization shall retain documented information on the delivery of products. This information shall include the following. a) Proof of conformance with the management criteria of chemicals in products b) Traceability to the person(s) authorizing the delivery The organization shall also manage product warehouses to prevent incorrect shipment and contamination. The organization shall consider matters such as the laws, regulations and industry criteria covered by the management criteria for chemicals in products, any nonconformance and the feedback from customers and shall also decide and implement the action to be taken after delivery for the products supplied.	
5.5.8 Response to occurrence of nonconformity	4
The organization shall decide and document the methods to be used when nonconformity in chemicals in products occurs, to quickly contact persons within the organization, suppliers, outsourcing contractors and customers and to take temporary corrective action. After the temporary measure is taken, the organization shall investigate and identify the cause and determine and implement the necessary countermeasures to prevent recurrence. The organization shall take preventive measures to avoid any occurrence of nonconformity. The organization shall retain documented information on the action when a nonconforming product occurs.	
5.6 Performance evaluation and improvement	4
The organization shall evaluate the following items at predetermined intervals. The organization shall implement corrective action for matters which require correction. The organization shall retain the results of evaluations and corrective action as documented information and shall report the results to top management. The top management shall review those results of evaluations and corrective action. a) Situation of improvements b) Changes in external and internal issues related to the management of chemicals in products c) Information on management performance and effectiveness with regard to chemicals in products, including regarding the following trends: 1) Relevant communication with external stakeholders 2) Level of target achievement 3) Conformance with the management criteria of chemicals in products 4) Nonconformity and corrective action 5) Performance evaluation results 6) Supplier and external outsourcing contractor performance d) Suitability of resources e) Effectiveness of actions to address risks and opportunities f) Improvement planning	

Annex E: Check Sheet

The Check Sheet is provided as an Annex in the Guidelines and it can be used by the organizations which are practicing management of chemicals in products in accordance with these Guidelines. The Check Sheet is provided in Microsoft Excel format.

The intention of these Guidelines is to enhance the management level of chemicals in products by commonly referring to the Guidelines in the entire supply chain and concurrently to reduce the workload of the organizations concerned. Therefore, organizations that use the Check Sheet must observe the rules of use. Amending the Check Sheet is not allowed. “The cover” and “the Check Sheet” are prepared in Microsoft Excel format and the organization is only allowed to key in data into specified cells. When the organization needs to add notes such as supplementary explanation, the organization can add another sheet in the same file.

The organization can customize the check sheet such as keying in additional data into specified cells or adding another sheet to provide information in advance such as information from the evaluation requester. Furthermore, the organization is able to provide the check sheet by email or publish it in the website. In such a case, the organization is required to disclose the information indicating where the original check sheet is kept.

The following pages show images of “1. The cover” and “2. Check Sheet” sheets.

Guidelines for the Management of Chemicals in Products (CiP) (Version 4.0) - Annex Check Sheet (Version 4.01) (Front cover)

Date of Entry:

Self-Evaluating Organization		* <Company name>, <Site name> and <Date of Self-Evaluation> are linked to the field in "2. Check Sheet." Hence, it is not necessary to enter information in this sheet.
Company name	Japanese	
	English	
Site name	Japanese	
	English	
Date of Self-Evaluation		
Address		
Product		
P. I. C. of data entry	Department	
	Job Title	
	Name	
	Contact	E-mail
		Tel

Standards	Date of Certification *1	Certification body	Certification No.	Validity Period of Certification
ISO9001				
ISO14001				
IEC QC 080000				
Others *2				

*1: Date of Certification: If the organization is not yet certified, but the acquisition of certification is planned, enter the planned acquisition date.
*2: Enter if the organization has certified with any other standards.

					by Self-Evaluating Organization				by Evaluation-Result Verifying Organization			
	Evaluation Item	Question level	No. of Questions		conformity	Partial conformance	nonconformity	Non applicable	conformity	Partial conformance	nonconformity	Non applicable
Evaluation Result	5.1.3 Determining the scope of the CiP management	**Basic**		1								
		Advanced	1									
	5.2.2 Policy	**Basic**	1	1								
		Advanced										
	5.2.3 Roles, responsibility and authority of an organization	**Basic**	1	1								
		Advanced										
	5.3.2 Objectives and planning to achieve them	**Basic**	3	3								
		Advanced										
	5.4.2 Competence	**Basic**	1	1								
		Advanced										
	5.4.5 Documented information	**Basic**	1	2								
		Advanced	1									
	5.5.2.1 Customer communication	**Basic**	2	2								
		Advanced										
	5.5.2.2 Defining the CiP management criteria	**Basic**	1	1								
		Advanced										
	5.5.3 CiP Management in design and development	**Basic**	1	1								
		Advanced										
	5.5.4.1 CiP information collection and verification	**Basic**	5	7								
		Advanced	2									
	5.5.4.2 Verification of the CiP management status at suppliers	**Basic**	5	10								
		Advanced	5									
	5.5.4.3 CiP management at receiving	**Basic**	2	2								
		Advanced										
	5.5.4.4 Verification of the CiP management status at outsourcing organization	**Basic**	2	3								
		Advanced	1									
	5.5.5.1 Management in manufacturing processes (Management of conversion process)	**Basic**	2	3								
		Advanced	1									
	5.5.5.2 Prevention of incorrect use and contamination (Management of incorrect use and contamination for parallel production and prohibited substances)	**Basic**	4	5								
		Advanced	1									
	5.5.5.3 Identification and traceability	**Basic**	1	1								
		Advanced										
	5.5.6 Change management	**Basic**	4	4								
		Advanced										
	5.5.7 Delivery of products	**Basic**	1	1								
		Advanced										
	5.5.8 Response to occurrence of nonconformity	**Basic**	4	4								
		Advanced										
	5.6 Performance evaluation and improvement	Basic	3	4								
		Advanced	1									
	Total	Basic	44	57								
		Advanced	13									
		Basic + Advanced										

Evaluation-Result verifying organization	* <Company name>, <Department>,,<Name> <Job Title> and <Date of Verification of Evaluation-Result> are linked to the field in "2. Check Sheet." Hence, it is not necessary to enter information in this sheet
Company name	
Department name	
Job Title	
Name	
Date of Verification of Evaluation-Result	

Final judgment	

Guidelines for the Management of Chemicals in Products (CiP) (Ver. 4.0)
Annex Check Sheet (Ver. 4.01)

< > *1
Materials attached (Yes / No)

* This Check Sheet abbreviates "chemicals in products" to "CiP."
(CiP: Abbreviation of Chemicals in Products)

*1: The user can edit this Check Sheet by adding to the question flag (*Select field) or attaching new sheets, in accordance with "3. Check sheet use and rules." The title can be entered in this field if the Check Sheet is edited

Self-Evaluating Organization		
Company name	Japanese	
	English	
Site name	Japanese	
	English	
Date of Self-Evaluation		

Evaluation-Result verifying organization	
Company name	
Department name	
Job Title	
Name	
Date of Verification of Evaluation-Result	

[Evaluation Result]

Question Flag	No. of Questions	Self-Evaluating Organization				Evaluation-Result verifying organization			
		conformity	Partial conformance	nonconformity	Non applicable	conformity	Partial conformance	nonconformity	Non applicable
Basic level	44	0	0	0	0	0	0	0	0
Advanced level	13	0	0	0	0	0	0	0	0
Total	57	0	0	0	0	0	0	0	0

[Select Evaluation Result]

Question Flag	No. of Questions	Self-Evaluating Organization				Evaluation-Result verifying organization			
		conformity	Partial conformance	nonconformity	Non applicable	conformity	Partial conformance	nonconformity	Non applicable
Select	59	0	0	0	0	0	0	0	0
Evaluation result score / No. of applicable evaluation items	--	0%	0%	0%	--	0%	0%	0%	--

* No. 36 and No. 41 are set such that the answer is yes or no, so the total number of questions above and the total for each judgment may not be equal.

[Final verification result]	[Comment]

[Description of Terms]

Action Items	These are specific descriptions of the items necessary to implement CiP management appropriately and efficiently, based on the JIS Z 7201:2017 "Management of Chemical Substances in Products - Principles and Guidelines." It is assumed that the Guidelines for the Management of CiP are referenced in the construction of CiP management. The specific details of what should be implemented are described for the action items. In accordance with the action items in the main text of the Guidelines for the Management of CiP, expressions such as "is doing **" are used to make it possible to judge conformance. [Regarding "No question so answer not required"] This item overlaps with other items, so no question is necessary in this item and it is not subject to evaluation.
Questions	These replace the questions with specific questions for the purpose of verifying whether or not the action items (details) are appropriately and effectively implemented. It is important that a common language is used for this section throughout the entire supply chain. However, depending on the nature of the business operation, some items may not be appropriately expressed. In such a case, it is necessary for the organization to implement "Action items (Details)" that are suitable for the nature of the business, such as by replacing the details as necessary. If the "Action item" is not applicable to the organization, then it is not necessary to implement that action item (non-applicable). The questions have been split into a Main Classification and Sub-Classification to aid understanding. For an explanation of each classification, refer to 3. Check sheet use and rules. <About the Question Flags> [Basic level] "++" => These are set automatically as the criteria for issuing a Self Declaration of Conformity. • These are basic management requirements under the CiP management system. (Questions based on the JIS Z 7201 CiP management guidelines) • Milestones for the construction of the management system that should be constructed and maintained for reliable and efficient CiP management [Advanced level] "++" => These are set automatically as the level of the next steps. • Requirements for the management system that should be constructed and maintained for reliable and efficient CiP management [*Select] "++" => These are set by the Evaluation-Result verifying organization when required. Example: [xx Co., Ltd. - questions to be answered for self-evaluation / xx Co., Ltd. - compulsory questions, etc.] *For details, refer to "3. Check sheet use and rules." This field can be edited freely by the check sheet user (First party (e.g. product supplier), second party (e.g. product purchaser or industry organization), etc.). Please enter the title of the flag and add an explanation. Example: When a "++" is marked in the field of xx Co., Ltd. - compulsory questions, an answer must be provided.
Conformance judgment criteria, sample answer, points to note in management	Conformance judgment criteria: For the criteria for the judgment of conformance written in the Entry Requirements, write guidelines for the judgment of conformance, partial conformance and nonconformance for each question. Sample answer: Write a sample answer in accordance with the intention of each question for reference. Points to note in management: Write information useful as a reference when judging conformance for the question concerned.
by Self-Evaluating Organization	In order to verify the self-evaluation result of each question and the outcome of answers more specifically, implementation details and an evidence name shall be entered for verification. If the reply details do not fit to the reply field, then write details in line with the operations. [Regarding items with no questions] Evaluation is not necessary. Things noticed about these items during the self-evaluation can be written in the response field to be useful during the next evaluation.
by Evaluation-Result Verifying Organization	This field is used when the organization evaluated or a separate organization such as a customer conducts audit verification or judgment based on the outcome of the answers by the self-evaluating organization. Write the judgment for each question and write the reason and any notes for that judgment.

[Entry Requirement]

Step (1): Conduct self-evaluation for applicable action items. The self-evaluation shall be performed based on "Table 6-2 Judging criteria for conformance to action items" in these guidelines and the <Judging Criteria of Conformance to Questions> table below. Select one of "Conformance," "Partial conformance" or "Nonconformance" in the field of "Self-Evaluation Result."
(If using Excel for data entry, select from pull-down.) If the question is not applicable, select "Non-applicable."

<Judging Criteria of Conformance to Questions> *Where criteria for the judgment of conformance are written for a question, use those criteria as guidelines for the judgment.

conformity	For the question details, judge that there is "Conformance" if the operation is properly practiced in accordance with the rules. If "documented information" is demanded in the question, then include confirmation of whether or not that information exists.
Partial conformance	For the question details, judge that there is "Partial conformance" if there is partial deficiency in the rules or the operation. In either case, it is important that the actual operations compensate for the deficiency and the status is almost at the level of conformance. In the case of a "Partial conformance" judgment, it is necessary to clarify the deficiencies and indicate plans for improvement or the necessity for such plans.
nonconformity	If there is no rule corresponding to the question and/or if no such operation is carried out, then the judgment for the question concerned is "Nonconformance."
Non applicable	When the "Action item" or "Question" is not applicable to the organization, it can be excluded from the evaluation as "Non-applicable." However, the reason for "non-applicable" needs to be specified.

Step (2): As an answer ("Implementation details, evidence name" field), enter implementation details that are reasons for implementation and/or a name of evidence. If an item is non-applicable, write the reason in each case to the extent possible.

* Although documents or others may be submitted or may be requested as objective grounds, the Guidelines do not necessarily assume this. For the purpose of verifying the CiP management system, the organization may request disclosure of the verification record. In such cases, it is desirable that the verification records be disclosed after mutual consultation. In addition, sufficient caution is required to protect confidential business information.

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

No	Action Items (Details)						Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization		by Evaluation-Result Verifying Organization	
	Main Classification	Sub-Classification	Question Flag: Basic	Question Flag: Advanced	Question Flag: *Select				Self-Evaluation Result	Answer (Implementation details, evidence name, etc.)	Judgment Result	Judgment reason, memo, remarks, etc.
5.1 Context of the organization												
5.1.1 Understanding the organization and its context												
	The organization shall clarify external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its CiP management.											
-	Reference	Reference					(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.1.2 Understanding the needs and expectations of stakeholders												
	The organization shall clarify the following items to understand the needs and expectations of stakeholders. **a) The stakeholders closely related to CiP management** **b) The requirements of those stakeholders that are closely related to CiP management**											
-	Reference	Reference					(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.1.3 Determining the scope of the CiP management												
	The organization shall determine the appropriate scope of application of CiP management. When determining this scope, the organization shall consider: **a) The external and internal issues for the organization defined in 5.1.1** **b) The requirements of stakeholders defined in 5.1.2** **c) The relationship between the organization and chemical substances** **d) The externally provided products handled by the organization and the products delivered to external parties** **The scope of application of CiP management shall be put in a state that can be used as documented information.**											
1	Common management	Verification of implementation	++	++			Do you have a clear scope where the CiP management system is applied?	<Conformance judgment criteria> Conformance: The organization to perform CiP management and the products and processes concerned are documented Or else, it is acceptable to just define the scope of items to be excluded from the management. Partial conformance: There are points that are not clarified regarding the organization or processes. The handling of the protective materials for products or the tools and jigs, etc., is unclear. Nonconformance: It has not been documented. The scope of application has not been defined. <Sample answers> a) CiP management regulations b) Outline Management is conducted for the products for which product planning, development or production is conducted by xx Co., Ltd., and for all the packaging materials for those products. However, items are excluded from management when specified by customer request. <Points to note in management> • By considering the items a) to d) written in the action items, the scope of application can make it possible to prevent omissions in the management and conduct effective activities.		Enter the name of the document in which the scope of application is written and an outline. (a) Documented information name: (b) Outline:		

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

Action Items (Details)

No	Item Classification	Sub-Classification	Question Flag: Basic	Question Flag: Advanced	Question Flag: *Select	Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization: Self-Evaluation Result	by Self-Evaluating Organization: Answer (Implementation details, evidence name, etc.)	by Evaluation-Result Verifying Organization: Judgment Result	by Evaluation-Result Verifying Organization: Judgment reason, memo, remarks, etc.
5.1.4 Implementation of CiP management											
	The organization shall establish, implement, sustain and continuously improve the CiP management system in accordance with the basic thinking and action items for CiP management stated in the Guidelines. For the purpose of producing products which can fulfill the CiP management criteria, the organization shall operate the CiP management in accordance with the type of business operation, at each stage of design and development, purchasing, manufacturing and delivery.										
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.2 Leadership											
5.2.1 Leadership and commitment											
	Top management shall demonstrate leadership and commitment with respect to the CiP management by: a) Taking accountability for the effectiveness of the CiP management. b) Positioning CiP management as an activity of the organization. c) Making the necessary resources available for use (Refer to 5.4.1). d) Ensuring compliance with the CiP management criteria.										
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.2.2 Policy											
	The top management shall establish the CiP management policy for the organization and shall formulate, implement and sustain plans based on that policy. Furthermore, the top management shall state that it will appropriately implement the CiP management.										
2	Common management	Verification of Implementation and Dissemination	++		++	Do you have a clear CiP management policy? (a) Has the top management declared its policy for the appropriate implementation of CiP management? (b) Has it been disseminated to the concerned departments?	<Conformance judgment criteria> Conformance: The top management has indicated its intentions regarding CiP management. *As shown in the sample answers, it is clear what kind of framework will be used in the company to implement CiP management. Nonconformance: There has been no indication of the intentions of top management regarding CiP management. <Sample answers> (a) xxx Co. Ltd. Quality policy and/or Environment policy and/or CSR policy (website also possible) (b) • Disseminated via a website that related parties can view • Released to the general public on the company website <Points to note in management> • It is preferable that the policy includes matters such as the observance of laws and regulations and action for industry standards and that it is maintained with reviews conducted as necessary.		Enter the name of policy document which defines the CiP management policy. (a) Document declaring policy, etc.: [(b) The method of dissemination: [		
5.2.3 Roles, responsibility and authority of an organization											
	In order to implement effective CiP management, the top management shall define the responsibilities and authorities for the relevant roles and communicate this within the organization.										
3	Common management	Verification of Implementation and Dissemination	++		++	Are the roles and departments related to CiP management clearly defined? Have you: (a) Clarified the departments related to CiP management, (b) Defined the responsibility and authority for the roles, and (c) Disseminated these?	<Conformance judgment criteria> Conformance: When all of (a), (b) and (c) are implemented. Partial conformance: When two of (a), (b) and (c) are implemented. Nonconformance: When only one item or less is implemented. <Sample answers> (a) Work regulations Article *** and CiP management regulations Article ***: Roles, responsibilities, authority, etc. (b) Product environment committee regulations Article *** and CiP management regulations Article ***: Roles, responsibilities, authority, etc. (c) The person responsible for the department stores the work allocation regulations, the product environment committee rules are published on the Intranet and the committee members extend them throughout the department		Enter the names of the documents which define the departments related to CiP management and their roles, responsibilities and authority and enter the method for disseminating these. (a) The name of the document that defines the departments related to CiP management and their roles: [(b) The name of the document that determines the responsibilities and authority of the departments related to CiP management with respect to that role: [(c) The method of dissemination of the roles in (a) and (b): [		
5.3 Plan											
5.3.1 Actions to address risks and opportunities											
	When formulating a plan for CiP management, the organization shall consider the external and internal issues for the organization defined in 5.1.1, the requirements of stakeholders defined in 5.1.2 and the scope of application defined in 5.1.3 and shall decide the risks and opportunities that must be approached as listed below to realize the intended results of the organization. a) Make it possible for CiP management to achieve the intended results. b) Enhance the desirable effects. c) Prevent or reduce the undesired effects. d) Promote continuous improvement. The organization shall plan their actions to address risks and opportunities according to the above.										
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.3.2 Objectives and planning to achieve them											
	The organization shall set the target for CiP management. The organization shall draw up, implement and sustain the plan to achieve the target. The organization shall review the target and the implementation plan whenever needed. When formulating a plan, the organization shall consider: a) The integration of the actions to address risks and opportunities (5.3.1) into CiP management, the implementation of the actions and the evaluation of their effectiveness b) Points of improvement from performance evaluation										
4	Common management	Verification of Implementation	++		++	(1) Have you set targets and created plans for their achievement?	<Conformance judgment criteria> Conformance: A plan that defines the targets has been created. Partial conformance: The targets have been created, but no plan has been created. Nonconformance: Neither targets nor a plan have been created. <Sample answers> • Chemical substance inspection plan • Supplier evaluation plan <Points to note in management> • The integration of the actions to address risks and opportunities (5.3.1) into CiP management, the implementation of the actions and the evaluation of their effectiveness have been included in the plan.		(1) Enter the name of the document in which the plan with defined targets is written and the name of the record where the implementation status is recorded.		
5	Common management	Review Checks	++		++	(2) Do you review the target or the implementation plan whenever it is required?	<Conformance judgment criteria> Conformance: The timing for the reviewing of targets and implementation plans is defined and operated. *If the review criteria are not met, then it will be conformance if the reviews are not conducted. Partial conformance: There are deficiencies in either the criteria or the implementation of the reviews of the targets and implementation plans. Nonconformance: There are no criteria for reviews of the targets and implementation plans, or there are no such operations. <Sample answers> • Target revision: 20**/**/** • Plan revision: 20**/**/**		(2) Enter the date when the latest revision of the target and the implementation plan was implemented. If there are no previous results, then enter the timing of the review.		
6	Common management	Verification of Dissemination	++		++	(3) Do you disseminate the target and the implementation plan to the departments concerned?	<Conformance judgment criteria> Conformance: There are specific measures for dissemination. Partial conformance: There are issues for the measures. Nonconformance: There have been no measures. <Sample answers> • The targets and implementation plans are published on the Intranet and awareness is spread to related departments when revisions are made.		(3) Enter the method to disseminate the target or the implementation plan.		
5.4 Support											
5.4.1 Resources											
	The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the CiP management.										
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.4.2 Competence											
	The organization shall conduct the following items for competence. a) Clarify the competence required for persons involved in CiP management at each stage of design and development, purchasing, manufacturing and delivery. b) Ensure that the persons involved in CiP management are competent on the basis of appropriate education/training or experience. c) Retain documented information on the implementation of education and training.										
7	Common management	Verification of Implementation and Recording	++		++	(a) Have you defined the persons to receive training and the contents of the education/training for each item of operation and management? (b) Do you conduct and record education and training?	<Conformance judgment criteria> Conformance: It is implemented and recorded based on documented information that defines the implementation of education and training. Partial conformance: There are deficiencies in the documented information such as omissions. Nonconformance: There are no rules regarding education and no previous results. <Sample answers> (a) "CiP management regulations" (Document No. xxxx Revision 01) Item No. xx : Education and training (b) Target staff: [Person in charge of materials, person in charge of manufacturing] Contents of training: [Identification management at parallel production (Storage, production switching, cleaning, etc.)] Records: [Education records, course attendance records, etc.] <Points to note in management> • If there is a document that defines the rules for education and training related to CiP management and the recording, then it is acceptable to write the name of that regulation.		Enter the document that defines the operation rules for education and training and enter the persons who require education and the contents of the training. (a) Name of document that defines the operation rules for education and training [(b) Training contents and records for main individual education 1) Target staff: [Contents of training: [Record: [2) Target staff: [Contents of training: [Record: [3) Target staff: [Contents of training: [Record: [		

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)													
Action Items (Details)													
No	Item Classification	Sub-Classification	Question Flag: Basic	Question Flag: Advanced	Question Flag: *Select	Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization: Self-Evaluation Result	by Self-Evaluating Organization: Answer (Implementation details, evidence name, etc.)	by Evaluation-Result Verifying Organization: Judgment Result	by Evaluation-Result Verifying Organization: Judgment reason, memo, remarks, etc.
5.4.3 Awareness											
The organization shall ensure that persons involved in CiP management are aware of: **a) The CiP management policy** **b) The targets for the relevant CiP management** **c) The risks related to their own work that require attention** **d) Their contribution to the effectiveness of the CiP management system, including the benefits of improved performance.** **e) The meaning of the nonconformance of the CiP management with the basic thinking and action items for CiP management.**											
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.4.4 Communication											
The organization shall determine the internal and external communication of the organization relevant to the CiP management, including: **a) The contents of communication** **b) Implementation timing** **c) Target persons** **d) Implementation methods** **e) Staff responsible**											
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.4.4.1 Internal communication											
For the information related to CiP management, the organization shall establish and implement procedures related to communication between the various levels and functions (departments) of the organization.											
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.4.4.2 External communication											
For the information necessary for CiP management, the organization shall establish and implement procedures related to communication with external parties.											
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.4.5 Documented information											
The organization shall maintain or retain the documented information recommended in the Guidelines and also the documented information defined by the organization to be necessary for the effectiveness of CiP management.											
8	Common management	Verification of Implementation	++		++	(1) Do you manage the documents related to CiP management (the documents verified in this check sheet)?	<Conformance judgment criteria> Conformance: There is documented information defining the documents that must be managed and the method for management. Partial conformance: There are deficiencies in the contents written such as omissions. Nonconformance: There is no documented information defining the documents that must be managed and the method for management. <Sample answers> • "XX Co. Ltd. CiP document system diagram" • "XX Co. Ltd. List of CiP related documents" <Points to note in management> • It is recommended that documents are managed systematically using a list of documents or a document system diagram, etc. • In the document system, the revision history of each document shall be specified. • Documentation on CiP management should be kept in an environment where authorized persons are able to view and verify the latest version, and documentation should be reviewed whenever necessary.		(1) Enter the documented information that shows the system and management method for documents related to CiP management (the documents verified in this check sheet).		
9	Common management	Verification of Recording		++	++	(2) Do you store operation records related to CiP management?	<Conformance judgment criteria> Conformance: There are records of the items managed by the company. Partial conformance: There are omissions in the records of the items managed by the company. Nonconformance: There are no records of the items managed by the company. <Sample answers> • Product assessment report (Retention period xx years) • Supplier evaluation results (Retention period xx years) • Outsourcing organization evaluation results (Retention period xx years) • Receiving inspection performance sheet (Retention period xx years) • Test piece analysis report (Retention period xx years) • Identification tag (Retention period xx years) • Lot management record (Retention period xx years) • Receiving verification record for the customer's green procurement criteria, etc. (Retention period xx years) • Record of CiP information survey responses (Retention period xx years) • Record of responses to evaluations by customers concerning CiP management (Retention period xx years) • Application for process change (Retention period xx years) • CiP - Survey and judging staff training (Retention period xx years) • Internal audit report (Retention period xx years) • Management review report (Retention period xx years) <Points to note in management> • Operation record means a verification record for respective items. • The company shall set a retention period for each operation record and manage it accordingly. • If a retention period is regulated by a law or as a customer requirement, then the company shall set the retention period accordingly.		(2) Enter the names of the records kept by the company and their retention periods. * If the space is not enough to list all the records in this cell, then an existing record (such as a management list of records, etc.) can be used as an alternative.		
5.5 Operation											
5.5.1 Operational planning and control											
The organization shall plan, implement, manage and maintain the processes necessary to satisfy the CiP management criteria and to implement the actions determined in 5.3.1. (Refer to 5.1.4.) **The organization shall retain the level of documented information necessary to verify that the processes have been implemented in accordance with the plans.** **The organization shall ensure that outsourced processes are being managed (Refer to 5.5.4).**											
-	Reference	Reference				(No questions)			(No question so answer not required)		(Not subject to evaluation)
5.5.2 CiP management criteria formulation											
5.5.2.1 Customer communication											
The organization shall clearly define and implement effective methods for communication with the customer for the following matters, and retain the details as documented information. **a) The acquisition of information on the laws, regulations and industry standards that the customer must comply with** **b) The provision of CiP information** **c) The provision of information on CiP management** **d) The acquisition of feedback from the customer on products, including complaints** **If any change is to be made to the CiP information, the organization shall notify the customer prior to such a change.**											
10	Common management	Verification of Implementation	++		++	(1) For the applicable items of a) to d) below, do you have and also implement effective methods for communicating information to customers and suppliers and for information exchange? (a) Acquisition of laws, regulations and industry standards that must be observed by the customer or supplier (b) Provision of CiP information (c) Provision of information related to CiP management (d) Acquisition of feedback from the customer, including complaints	<Conformance judgment criteria> Conformance: There is a procedure defining the details (a) to (d) for communication with the customer and it is operated. Partial conformance: There are deficiencies such as some items are not implemented (have no procedure). Nonconformance: There is no procedure defining the communication with the customer and it is not implemented. <Sample answers> (a) Document stipulating the laws, regulations and industry standards that must be observed by the customer: Management standards for CiP related laws and regulations to be observed (b) Document stipulating the CiP information: CiP rank guidelines management procedure (c) Document stipulating the rules for the provision of information related to CiP management: CiP information management and provision method regulations (d) Document stipulating the management of information such as complaints from customers: Complaint handling management procedure <Points to note in management> • An effective method of information exchange means that an effective system has been established in order to give a quick response to enquiries or evaluations.		(1) Enter the document which defines the method for efficient information exchange with the customers and suppliers for (a) to (d) below. (a) Laws, regulations and industry standards that must be observed by the customer [(b) CiP information: [(c) Information related to CiP management: [(d) Complaints from customers: [		
11	Common management	Verification of Recording	++		++	(2) Do you record the details in (1) above?	<Conformance judgment criteria> Conformance: There are records for all the procedures in the previous item. Partial conformance: There are deficiencies such as omissions in the management. Nonconformance: There is no management of records. <Sample answers> (a) Laws, regulations and industry standards that must be observed by the customer [Receiving verification record for the customer's green procurement criteria, etc.] (b) CiP information: [Record of CiP information survey responses] (c) Information related to CiP management: [Record of responses to evaluations by customers concerning CiP management] (d) Information related to complaints from customers [Record of responses to complaints from customers]		(2) Enter the name of the record that will be the evidence. (a) Laws, regulations and industry standards that must be observed by the customer [(b) CiP information: [(c) Information related to CiP management: [(d) Information related to complaints from customers: [		

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)												
Action Items (Details)												
No	Item Classification	Sub-Classification	Question Flag: Basic	Question Flag: Advanced	Question Flag: *Select	Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization: Self-Evaluation Result	by Self-Evaluating Organization: Answer (Implementation details, evidence name, etc.)	by Evaluation-Result Verifying Organization: Judgment Result	by Evaluation-Result Verifying Organization: Judgment reason, memo, remarks, etc.
5.5.2 Defining the CiP management criteria											
The organization shall determine the CiP management criteria for products and maintain them as documented information. When clarifying the CiP management criteria, the organization shall define the details of items to be implemented, including: a) The requirements of legal regulations b) The identification of stakeholders related to CiP management and their requirements and expectations c) Other items considered necessary by the organization											
12	Common management	Verification of Criteria Existence and Documentation	++		++	Are there CiP management criteria that satisfy the requirements below and is there a document that defines the implementation procedures? (a) The chemical substances subject to management are listed (b) The management level is clearly stated in the criteria (c) The applicable laws, regulations and industry standards are clarified (d) The criteria are reviewed as necessary or periodically (e) The criteria are communicated to the departments concerned	<Conformance judgment criteria> Conformance: When all of the requirements (a) to (e) are satisfied. Partial conformance: When one or more is satisfied. Nonconformance: When none are satisfied. <Sample answer> (a), (b) • "CiP management regulations" Item No. XXX: "CiP management/Prohibited substances list" <Sample answers> (c) • It is defined based on laws, regulations and industry standards. • It is defined based on the customer requirements. • It is set based on IEC62474DSL. • It is set based on GADSL. • It is defined based on the JAMP declarable substance list. • Action is taken based on JIG-101 and JIG-201. <Sample answer> (d) "CiP management regulations" Item No. XXX: "Reviewing criteria" <Sample answer> (e) • The latest version is published on the Intranet and awareness is spread to related departments when revisions are made. * Questions based on "4.3.4 Internal Communication" stated in JIS Z 7201 CiP Management - Principles and Guidelines <Points to note in management> • In the case when the organization declares no possibility of inclusion in products based on scientific grounds, this does not have to be reflected in the management criteria, but the evidence or the facts must be provided. • The management level means the level of "prohibited to use" or "management of contained chemicals," etc. • CiP management criteria are necessary for the management of entrusted production too.		Enter the names of the CiP management criteria and procedures which specify the chemical substances subject to CiP management and the management levels. (a) Name of document containing list: [(b) Name of document containing management levels: [(c) Reference standards: [(d) Name of document containing criteria review procedure: [(e) Name of document containing procedure for communication to related departments: [		
5.5.3 CiP Management in design and development											
For the purpose of producing products which can fulfil the CiP management criteria in the stage of design and development, the organization shall clearly define the CiP management criteria at each stage of purchasing, manufacturing and delivery in accordance with its own products and business operation type and shall put and maintain those management criteria in a state where they can be used as documented information.											
13	Process Control	Verification of Criteria Existence	++		++	When manufacturing a new product, the CiP management criteria below are defined before mass production starts (a) Management criteria at the purchasing stage (b) Management criteria at the manufacturing stage (c) Management criteria at the delivery stage *The design and development stage is not only work of the design and development departments	<Conformance judgment criteria> Conformance: The CiP management criteria are defined for each stage. Partial conformance: There are deficiencies in the CiP management criteria. Nonconformance: They are not defined. <Sample answers> (a) Purchasing stage: Indicated as required specifications for the specification documents and drawings, etc., for items purchased. (b) Manufacturing stage: The CiP management criteria for conversion and reaction processes where the concentration changes are established by the work instructor. (c) Delivery stage: The certified levels are indicated in the delivery specifications for end products. <Points to note in management> • Judgment and management should be conducted using the specifications during mass production. • There must be an awareness that there is a risk of exceeding the management standards if there is any conversion process, parallel production or use of recycled materials. • If the constituent components of the products are selected in-house at a company, then it has a "design function."		Enter the name of the document which defines the procedure for setting criteria for each individual product or the procedure for each stage. [* If the procedure is different for each stage, then enter the details below. (a) Purchasing stage: [(b) Manufacturing stage: [(c) Delivery stage: [		
5.5.4 Management of externally provided products											
5.5.4.1 CiP information collection and verification											
After first defining the action to be taken for the acquisition of CiP information and the results of verification, the organization shall then present the management criteria related to CiP in purchasing to the supplier and obtain the CiP information. The organization shall verify if the CiP information obtained satisfies the management criteria related to CiP in purchasing and shall retain the result as documented information. The acquisition and verification of CiP information in accordance with the management criteria related to CiP in purchasing should be completed before the manufacturing is started.											
14	Process Control	Verification of Criteria Existence	++		++	(1) Do you have management criteria for purchasing which specify the CiP management criteria and include the chemical substances and management level?	<Conformance judgment criteria> Conformance: The management criteria are defined and have been stated explicitly. Nonconformance: There are management criteria, but they have not been stated explicitly. Or else, there are no management criteria defined that include the chemical substances and management levels. <Sample answers> • A list of declarable substances (Green procurement criteria) has been created and the management criteria are defined. • The management criteria are also defined in the Green Procurement Chemical Substance Questionnaire • The management criteria are compliant with the RoHS directive and to be compliant is written on all drawings and purchasing contracts. <Points to note in management> • The packing materials, secondary materials and sub-materials that require CiP management shall also be subject to the purchase management criteria.		(1) Enter the name of the management criteria for purchasing or the name of materials equivalent to that or an outline of the management.		
15	Process Control	Verification of Dissemination	++		++	(2) How do you disseminate the "management criteria for purchasing" above to the suppliers?	<Conformance judgment criteria> Conformance: The timing and the means for the dissemination are defined and also the dissemination to suppliers is implemented. Nonconformance: The timing or the means for the dissemination are not defined, or else, the dissemination is not implemented. <Sample answers> (a) The method of dissemination: • The company sends "Green Procurement Criteria" to suppliers and obtains an acknowledgement of receipt for them. • Before starting new trade, the criteria are distributed in advance and compliance is requested. (b) Dissemination timing: • It is conducted when starting new trade and when the criteria are revised.		(2) Enter the method for the dissemination of "purchase management criteria" to suppliers and the timing of that dissemination. (a) The method of dissemination: [(b) Dissemination timing: [		
16	Process Control	Verification of Implementation	++		++	(3) Are there clear definitions of the timing, method and department (person) for the acquisition of the necessary CiP information from procurement sources after checking the necessity for all of the constituent elements of products and also a clearly defined verification method for constituent elements?	<Conformance judgment criteria> Conformance: There are clear definitions of the timing, method and department (person) for the acquisition of the necessary CiP information for all of the constituent elements of products and also the acquisition is implemented. Partial conformance: The information is acquired, but the timing or the method or the department (person) is not defined. Nonconformance: The information is not acquired. <Sample answers> (a) Acquisition timing: Limit set at time of request (per part), before starting mass production (per product) (b) Acquisition method: Obtained via email, etc. (c) Acquisition department: Engineer responsible for product (d) Method for verifying all constituent elements: The company verifies if all parts and materials are surveyed by linking the survey results to the BOM (bill of material) information for the product. Also, sub-materials which are not linked to the BOM (bill of material) are managed by using another list <Points to note in management> • When there is an element of the product's constituent elements that should be exempted from the survey, provide the reason for that exemption. Example: They are parts or materials that are specified by the customer and there is an agreement with the customer to exclude them from the survey. • The company has defined the person in charge, the procedure and the method to collect information on the chemical substances contained in purchased products (raw materials / parts and components).		(3) Enter the method used to verify that CiP information is obtained for all the constituent elements of products. *If this item is considered to be unnecessary for CiP management, then state the reason. (a) Acquisition timing: [(b) Acquisition method: [(c) Acquisition department: [(d) Method of verification of all constituent elements: [		
17	Process Control	Verification of Implementation		++	++	(4) Is there a defined format for the acquisition of the details reported on the CiP information that must be obtained in (3) above (such as whether or not there is inclusion, the content, concentration, purpose of use, etc.)?	<Conformance judgment criteria> Conformance: The format to be obtained from the supplier is clearly defined. Nonconformance: The format to be obtained from the supplier is not clearly defined. <Sample answers> • chemSHERPA • JAMA/JAPIA sheet • Certificate of non-use/Composition table <Points to note in management> • Check whether or not information is acquired that makes it possible to judge whether there is conformance or nonconformance to the management criteria.		(4) Enter the names of the survey formats. * If there are different formats for each type of material and part purchased, then list the format for each type of material and part purchased. Format name: [		
18	Process Control	Verification of Implementation	++		++	(5) For the CiP information obtained in (3) above, is it clear when, in what method and by which department (person) the situation of conformance with the management criteria is judged for each product purchased?	<Conformance judgment criteria> Conformance: It is stated explicitly that the information must be judged before the manufacturing is started, the method and department (person) for the judgment are clearly defined and also the judgment is performed and recorded. Nonconformance: The judgment method and department (person) are not defined, or else, the judgment is not performed. <Sample answers> (a) Document stipulating the judgment procedure: Regulations on the investigation of the chemicals included in parts and materials. (b) Judgment method: Per component - Verification of compatibility with internal criteria, Per product - Verification of whether the constituent components meet the internal criteria (c) Judging department: Person responsible for product environment (d) Judgment timing: Before delivery (e) Judgment record: Per component - Company-internal system (Component judgment), Per product - Company-internal system (Product judgment)		(5) Enter the method of judging the conformance status to the management criteria for each purchased product. Also provide the recording method. (a) Document stipulating the judgment procedure: [(b) Judgment method: [(c) Judgment department: [(d) Judgment timing: [(e) Judgment record: [		
19	Process Control	Verification of Implementation	++		++	(6) Is it clear what action should be taken if the information cannot be obtained in (3) above, or if the result of the judgment is that the purchase management criteria were not satisfied?	<Conformance judgment criteria> Conformance: There is an explicit description of the action to be taken if it was not possible to obtain the information, or else, if (in conclusion) the management criteria cannot be satisfied. Nonconformance: There is no explicit description of the action to be taken if it was not possible to obtain the information, or else, of the action to be taken if (in conclusion) the management criteria cannot be satisfied. <Sample answers> (a) Judgment timing: Before production starts (b) Document stipulating the judgment timing: CiP management criteria (c) Response if the information cannot be obtained, or if the management criteria are not satisfied: Make selection impossible. However, in the case when the information is not yet obtained, but it is judged using engineering knowledge that the criteria are satisfied, then make complementary use possible if that evidence is provided. (b) Document stipulating the response method: CiP management regulations <Points to note in management> • It is defined that if it does not conform to the management criteria, then the company shall take the necessary response such as "no purchasing."		(6) Enter the timing for judging the information acquired. Enter how to respond if the company fails to collect information, or if the purchase management criteria are not satisfied. Also enter the document defining these. (a) Judgment timing: [(b) Document stipulating the judgment timing: [(c) Response if the information cannot be obtained, or if the management criteria are not satisfied: [(d) Document stipulating the response method: [		

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

Action Items (Details)

No	Item Classification	Sub-Classification	Question Flag: Basic	Question Flag: Advanced	Question Flag: +Select	Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization: Self-Evaluation Result	by Self-Evaluating Organization: Answer (Implementation details, evidence name, etc.)	by Evaluation-Result Verifying Organization: Judgment Result	by Evaluation-Result Verifying Organization: Judgment reason, memo, remarks, etc.
20	Process Control	Verification of Implementation		++	++	(7) Do you judge the conformance status for each CiP information for your own company's products?	<Conformance judgment criteria> Conformance: For all products, the aggregation of CiP information is performed and also there is a record of the judgment of the product conformance status. Partial conformance: The aggregation and judgment of the CiP information is performed, but some of the records of past judgments cannot be found. Nonconformance: There is no record of the judgment of the conformance status being performed for a product. Or else, the judgment is not performed before starting the manufacturing. <Sample answers> (a) Aggregation record: CiP information aggregation results report/Chemical substance information management system product aggregation management screen (b) Judgment record: CiP information aggregation results report/Chemical substance information management system product aggregation management screen (c) Person responsible for approval: Manager of quality control department <Points to note in management> • Aggregation by each end product means to aggregate against the management criteria of chemical substances regulated in the "CiP management criteria." • Judgment of the conformance status means to judge the conformance status against the criteria defined in the "CiP management criteria" such as for the prohibition of use, etc.		(7) Enter the records of the aggregation and judgment of the CiP information and enter the person responsible for approval. (a) Aggregation record: [(b) Judgment record: [(c) Person responsible for approval: [		

5.5.4.2 Verification of the CiP management status at suppliers

The organization shall first define the action to be taken for the results of checks on the CiP management status at a supplier and then when selecting a supplier, the organization shall check that CiP management status and retain the result as documented information.
Even in cases when the organization is continuing purchases from a supplier, in order to fulfil the CiP management criteria, the organization shall verify the status of CiP management at the supplier again whenever necessary and retain the results as documented information.

No	Item Classification	Sub-Classification	Question Flag: Basic	Question Flag: Advanced	Question Flag: +Select	Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization: Self-Evaluation Result	by Self-Evaluating Organization: Answer (Implementation details, evidence name, etc.)	by Evaluation-Result Verifying Organization: Judgment Result	by Evaluation-Result Verifying Organization: Judgment reason, memo, remarks, etc.
21	Process Control	Verification of Implementation	++		++	(1) Do you request that suppliers establish and operate a CiP management system for the purpose of fulfilling the CiP management criteria?	<Conformance judgment criteria> Conformance: There is a document that requests that the suppliers establish and operate a CiP management system for the purpose of fulfilling the CiP management criteria. Partial conformance: There is a document that requests that the suppliers establish and operate a CiP management system for the purpose of fulfilling the CiP management criteria, but there are deficiencies in the details requested. Nonconformance: There is no request document. <Sample answers> • The company requests the establishment and operation of a system based on the "Guidelines for the Management of CiP." <Points to note in management> • A CiP management system for the purpose of satisfying the CiP management criteria means a system which can manage the chemical substances contained in products appropriately at each stage of purchasing, manufacturing and sales. Example: The main details required of those in note (1) in the "Guidelines for the Management of CiP (Ver. 4.0)" item 5.5.4.2 are as follows. A. Defining the management criteria B. CiP information acquisition and verification C. Verification of the management status at the supplier D. Verification at receiving E. Prevention of incorrect use, mixing in and contamination F. Appropriate management of conversion processes G. Traceability H. Change management I. Response to occurrence of nonconformance • If there is any exemption from the management, state its reason and specify the action. • Also include the case of purchasing from multiple suppliers in the scope.		(1) Enter the names of the CiP management regulations and criteria which you request from the supplier.		
22	Process Control	Verification of Implementation	++		++	(2) Do you verify the CiP management status at the supplier when you appoint a new supplier?	<Conformance judgment criteria> Conformance: There is a system for the verification of the CiP management status at a supplier when selecting a supplier and it is implemented. The system defines the details (criteria) to be verified and the verification method (procedure). Partial conformance: There is a system and it is implemented, but there are deficiencies in either the details (criteria) to be verified or the verification method (procedure). Nonconformance: There is no system (verification details and verification method). <Sample answers> (a) Verification details and items • Guidelines for the Management of CiP Ver. 4.0 Check sheet • Other check sheets • Verification of the system for no inclusion of prohibited chemical substances (b) Method of verification • Details including the above tools are verified by using email or checking the paper document. • When required, details including the above tools are verified at the supplier's location. • The company verifies the management status published in a website or other open source. <Points to note in management> • In the case of purchasing from multiple suppliers (multi-sourcing), each supplier must be included.		(2) Enter the verification details and the method of verification when the company appoints a new supplier. (a) Verification details and items: [(b) Method of verification: [		
23	Process Control	Verification of Implementation	++		++	(3) When you continue business with a supplier, do you re-verify the CiP management status periodically when required?	<Conformance judgment criteria> Conformance: There is also a system for CiP management periodically when continuing trade and it is implemented. The system defines the subject of the management, the frequency of verification, the details (criteria) to be verified and the verification method (procedure). Partial conformance: There is a deficiency in the subject of the management, the frequency of verification, the details (criteria) to be verified or the verification method (procedure). Nonconformance: There is no system (verification details and verification method). <Sample answer (Verification target)> (a) Verification targets • The company verifies all the suppliers. • Only the suppliers whom the company decides are necessary are subject to verification. (b) Verification details and items • Guidelines for the Management of CiP Ver. 4.0 Check sheet • Other check sheets • Verification of the system for no inclusion of prohibited chemical substances (c) Method of verification • Details including the above tools are verified by using email or checking the paper document. • When required, details including the above tools are verified at the supplier's location. • The company verifies the management status published in a website or other open source. (d) Frequency of verification • Once a year		(3) Enter the method of re-verification from the following points. (a) Verification targets: [(b) Verification details and items: [(c) Method of verification: [(d) Frequency of verification: [		
24	Process Control	Verification of Recording	++		++	(4) For (2) and (3) above, do you record the results of the verification of the CiP management status at the supplier?	<Conformance judgment criteria> Conformance: Records for (2) and (3) above are managed. Partial conformance: There are deficiencies in the recording or in the management of records. Nonconformance: There are no records. <Sample answers> • Judgment record • List of supplier evaluation results		(4) Enter the name of the record which shows the evaluation of the suppliers.		
25	Process Control	Verification of Implementation	++		++	(5) For (2) and (3) above, have you defined the action to take when the verification of the CiP management status is incomplete or when there is a problem in the verification contents or verification results?	<Conformance judgment criteria> Conformance: The details of the action to be taken for the target phenomena are defined. Nonconformance: The details of the action to be taken are not defined. <Sample answers> • The company takes action against the supplier such as to demand improvement, instruct on improvement or stop the trade. • The company instructs the supplier on improvement and also performs analysis on each individual lot until the improvements are complete, to verify that there are no problems with the products purchased.		(5) Enter the method of action when the verification of the management status is incomplete, or when a problem is found in the verification contents or verification results.		
26	Process Control	Verification of Implementation		++	++	(6) Does the supplier (first tier supplier) verify that the supplier of products it purchases (the second tier supplier) has constructed and operates a CiP management system?	<Conformance judgment criteria> Conformance: There is a document requesting the supplier (primary supplier) to further establish and operate the CiP management mechanism for suppliers (secondary suppliers) of purchased goods, and they operate it. Partial conformance: There is a request document, but there is no verification. Nonconformance: No requests are made. <Sample answers> • The evaluation check items used by the first tier supplier are verified and it is verified that the necessary items of CiP management are included. <Points to note in management> • It is effective if the verification contents are the same level as the requirements for the supplier (refer to the Points to note in management in (1) above) and there is a comment that this item should be included in the requirements.		(6) Enter your verification method (how you verify).		
27	Process Control	Verification of Implementation		++	++	(7) In your evaluations to determine a new supplier or to re-appoint an existing supplier, do you verify that the supplier inspects and identifies whether there is a process or material which may cause contamination with a prohibited substance specified in the CiP management criteria?	<Conformance judgment criteria> Conformance: There are appropriate management criteria defined for conversion processes and parallel production and it is verified that the contents are grasped without omissions based on the management criteria. Partial conformance: There are deficiencies in either the management criteria or the verification. Nonconformance: There are no management criteria defined for conversion processes and parallel production, or else, there is no record of verifications being performed. <Sample answers> • The following details are verified. 1) If there is any process in parallel production that may cause contamination by prohibited substances 2) If there is any solder bath that may cause contamination by prohibited substances		(7) Enter the details verified to identify if there is any process or any material at a supplier which may cause contamination by a substance defined as prohibited in the CiP management criteria.		
28	Process Control	Verification of Implementation		++	++	(8) In the results of the verification in (7) above, if there is a risk at a supplier of contamination with a prohibited substance specified in the CiP management criteria, do you verify if the supplier implements proper management to prevent that mixing in/contamination?	<Conformance judgment criteria> Conformance: There are management criteria defined to judge the appropriateness of conversion processes and parallel production at a supplier and judgments are made based on those criteria. * The scope of management and the appropriateness should be judged individually from the industry type, target processes, materials, etc., including regarding the necessity. Nonconformance: The management standards for suppliers are not defined. Or else, there is no record of verification being performed. <Sample answers> • Example of the management method when there is parallel production which may cause contamination by prohibited substances. Segregating the storage shelves for products containing prohibited substances or segregating product packaging (labeling, etc.). Isolating components and parts containing prohibited substances Parts and components containing prohibited substances are managed only by the authorized person. The company has verified that equipment, tools, jigs and containers that are used for components and parts containing prohibited substances, but are difficult to clean, are not used to produce components and parts which do not contain prohibited substances. For the purpose of preventing contamination, the company has defined the cleaning standards for cleanable equipment, tools, jigs and containers which are used for components containing prohibited substances. • Example of the management method for using recycled materials. Conducting analysis for every lot at receiving. • Example of the management method when there is a solder bath. Periodical analysis of solder bath		(8) Enter an example of a management method to prevent incorrect use and contamination that was judged to be appropriate.		
	Process Control	Verification of Implementation				(9) As a result of (8) above, when management cannot be verified at the supplier, do you verify and manage by yourself whether or not "purchased products fulfill the purchase management criteria"	<Conformance judgment criteria> Conformance: There are criteria for verifying the components purchased from suppliers for which the verification of management is not possible, and the criteria are operated appropriately. * For the appropriateness, judgments of the necessity of implementation, the details of evidence and the frequency, etc., should be made individually based on the industry type, target processes and materials, etc. Nonconformance: There is no system for verification. Or else, there is no record based on that system.		(9) Enter the evidence-based method of verification and management that your organization conducts by itself when the management at a supplier is not sufficient.		

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

No	Action Items (Details)			Question Flag			Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization		by Evaluation-Result Verifying Organization	
	Item Classification	Sub-Classification		Basic	Advanced	+Select			Self-Evaluation Result	Answer (Implementation details, evidence name, etc.)	Judgment Result	Judgment reason, memo, remarks, etc.
29	Process Control	Verification of Implementation			++	++	based on proper evidence?	<Sample answers> • Appropriate guidance is given if the management by the supplier is insufficient in cases when there is a risk of contamination by prohibited substances, such as in parallel production, recycled materials (pre-consumer materials, post-consumer materials (open/closed)) and solder bath concentration changes. • The company obtains analysis data and verifies that there is no mixing in of prohibited substances. <Points to note in management> Proper evidence is as shown in the following examples. • The company collects and verifies the analysis data for the initial delivery from the supplier and carries out periodical incoming analysis for every lot of products. • Periodical analysis of the end product • If a purchased product is a material, the company obtains the material certificate issued by the material manufacturer.				
30	Process Control	Verification of Documentation			++	++	(10) Do you have any documents that define the procedures to implement items (1) to (9) above?	<Conformance judgment criteria> Conformance: All the procedures for implementing (1) to (9) are documented. • If the result of the judgment of appropriateness is that implementation is not necessary for an item, then it is acceptable to set the self-evaluation results section as exempted. Nonconformance: When there is nonconformance for one or more of the items (1) to (9). <Sample answers> • Regulations of supplier management (Document No. xxxx Revision 01) Item No. xx : Requirements, Item No. xx: Updating evaluation, Item No. xx: Actions when evaluation is not conducted		(10) Enter the name and number of the document which defines the procedure to evaluate suppliers and also the item name and revision number.		

5.5.4.3 CiP management at receiving

The organization shall first define the action to be taken for the results of checks on the products purchased at the time of receiving. Then, at the time of receiving, the organization shall check that the management criteria of the organization related to CiP in purchasing are satisfied on the products purchased and shall retain the result as documented information.

31	Process Control	Verification of Implementation		++		++	(1) Do you verify whether or not the purchased products fulfill the purchase management criteria at receiving?	<Conformance judgment criteria> Conformance: It is verified that the criteria are satisfied for all of the products purchased. Partial conformance: There are omissions in the verification. Nonconformance: There is no verification conducted. <Sample answers> • The company verifies that the purchased products satisfy the purchase management criteria prior to issuing a purchase order. Therefore, the company inspects model names and model numbers against ordered items. <Points to note in management> • Receiving verification also includes products produced by the outsourcing contractor. • The company may select the verification targets, criteria, method and frequency depending on the risk level. • If the company has an ordering system which only allows the issuing of orders for parts/materials that are compliant with the management criteria, the company may inspect only order numbers or model names at receiving. • There are cases when there are risks in CiP management and cases when sub-materials such as product packaging materials are included in the scope, so caution is required.		(1) Enter the specific method of verification.		
32	Process Control	Verification of Recording		++		++	(2) Do you record the results in (1) above?	<Conformance judgment criteria> Conformance: There are records of the results of receiving inspections. Partial conformance: There are deficiencies in the records. Nonconformance: There is no system for records. <Sample answers> • Incoming inspection performance record, measurement record <Points to note in management> • If there are no previous purchasing results, conformance is possible if the documentation of the procedure has been completed and the format for the records is decided.		(2) Enter the name of the records where receiving verification is recorded.		

5.5.4.4 Verification of the CiP management status at outsourcing organization

If the organization outsources some processes such as product design and development or manufacturing to another organization, then the organization shall verify the CiP management status at the outsourcing organization to ensure that the CiP management criteria can be complied with and shall retain the result as documented information. The organization shall define the action to be taken for the verification results in advance.

33	Process Control	Verification of Implementation		++		++	(1) Do you communicate the management items/management contents for CiP management to the outsourcing organizations in writing, etc.?	<Conformance judgment criteria> Conformance: The management items/management contents for CiP management are communicated in documents, etc. Partial conformance: There are deficiencies such as omissions in the contents of the documents communicated. Nonconformance: There is no communication using documents. <Sample answers> • Production outsourcing agreement • Specifications • CiP management criteria <Points to note in management> • The company shall communicate the necessary management items/management contents for CiP management to the outsourcing organization as appropriate for the type of work outsourced. • When the company assigns the procurement of parts and materials to the outsourcing contractor, responsibilities and authorities have to be defined.		(1) Enter the name of the document used to communicate instructions to outsourcing organizations about the management method for CiP management.		
34	Process Control	Verification of Implementation		++		++	(2) Do you verify the implementation status of the details communicated in (1) above?	<Conformance judgment criteria> Conformance: The implementation status of the management items/management contents for CiP management is verified and recorded. Partial conformance: There are omissions or deficiencies in the verificaton details. Nonconformance: There is no verification conducted. <Sample answer (Verification details)> • Guidelines for the Management of CiP Ver. 4.0 Check sheet • The outsourcing contractor purchases the specified parts and materials from a genuine agent and produces under specified process conditions (production process, repair process, inspection process conditions, etc.) <Sample answer (Verification frequency)> • At least once every 2 years * However, depending on the risk of the outsourcing organizations, verification is done more frequently.		(2) Enter the verification details and the frequency of verification.		
35	Process Control	Verification of Documentation			++	++	(3) Do you have any documents that define the procedures to implement items (1) to (2) above?	<Conformance judgment criteria> Conformance: The management items/management contents for CiP management are documented and managed. Partial conformance: There are omissions or deficiencies in the details documented. Nonconformance: It has not been documented. <Sample answers> • "Outsourcing organization management regulations" Item No. xx: Information delivery, Item No. xx : Requirement, Item No. xx: Evaluation		(3) Enter the names of the documents and the items specifying the management method for "CiP management" for outsourcing organizations.		

5.5.5 CiP management in manufacturing and storage

5.5.5.1 Management in manufacturing processes (Management of conversion process)

The organization shall manage the manufacturing processes in accordance with the CiP management criteria for manufacturing processes and shall retain the results as documented information.

36	Process Control	Verification of Implementation		--	--	++	(1) In the manufacturing processes using chemical substances/compounds, is there a process (conversion process) where there is a composition change or concentration change and is there a risk that if the management of that process is not conducted appropriately, then a substance specified in the CiP management criteria may be generated or remain at a concentration exceeding the management criteria? * If the condition above does not apply, then enter "Non-applicable" for (2) to (4).	<Sample answers> (a) Applicable process: Electroless nickel plating (b) Material used: Plating solution (Ni 90 to 92%, P 8 to 10%, Pb 1000 ppm or below) (c) Declarable substances: Lead (d) Details of reaction: A very small amount of lead compound (which is added to stabilize a bath) goes into the film during the reaction. <Points to note in management> • Examples of the concentration changes and conversion processes where the declarable substances specified in the CiP management criteria may be generated or remain at levels exceeding the management criteria Polymerization (PVC: chemical reaction of vinyl chloride) Electroless nickel-plating process (Lead: Concentration change in plating solution) Ink paint (Lead, cadmium, etc.: Change in concentration due to volatilization of solvent, etc.) Sealant agent (DBT, DOT: Hardening reaction of two-component mixed type sealant) Baking/coating process Hardening and molding process for hardening resin		(1) If this question is applicable, enter the applicable process, the materials used and the reaction details. (a) Applicable process: [(b) Material used: [(c) Declarable substance: [(d) Reaction details: [		
37	Process Control	Verification of Criteria Existence		++		++	(2) For the applicable process in (1) above, have you defined the management criteria related to CiP in the manufacturing process?	<Conformance judgment criteria> Conformance: The management criteria for conversion processes are defined appropriately. Partial conformance: There are some deficiencies in the management criteria. Nonconformance: There are no management criteria defined. * The judgment of appropriateness is judged by the judge with reference to knowledge and product guidelines, etc. <Sample answers> (a) The document that defines the management criteria for the stage of manufacturing: [Operation Manual of Plating Process] (b) Specific method of management: [In order to regulate the lead added into the plating solution as a stabilizer, the company set the criteria value of lead (Pb) at "xxx ppm" and analysis of the liquid is carried out monthly for verification] <Points to note in management> • In the case of the manufacturing of chemical substances/mixtures, do you define the purchasing conditions, the manufacturing process, the manufacturing conditions, the inspection and shipping conditions in order to satisfy the management criteria for products with consideration of the chemical substances/mixture contained in raw materials or secondary materials and chemical substances added, generated and removed in the process? • In the case of the manufacturing of articles using chemical substances/mixture, do you design products or a process while focusing on a change in concentration of chemical substances or a change in the type of chemical substances contained in articles during the process based on logical reasons? * This applies when solder, adhesive, grease or ink, etc. is used in the process. • It is acceptable if "the management criteria for CiP management in the stage of manufacturing" are reflected in the QC process chart, management process diagram, management flow diagram, or operation procedures, etc.		(2) Enter the document specifying the management criteria in the manufacturing stage for the applicable process and also state the specific method of management. (a) Document defining the management criteria in the manufacturing process: [(b) Specific method of management: [		

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)														
Action Items (Details)														
No	Item Classification	Sub-Classification	Question Flag: Basic	Question Flag: Advanced	Question Flag: +Select	Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization: Self-Evaluation Result	by Self-Evaluating Organization: Answer (Implementation details, evidence name, etc.)	by Evaluation-Result Verifying Organization: Judgment Result	by Evaluation-Result Verifying Organization: Judgment reason, memo, remarks, etc.
38	Process Control	Verification of Recording	++		++	(3) Do you record the results of the management in (2) above?	<Conformance judgment criteria> Conformance: There is management of the records of judgments performed with the management criteria for conversion processes. Nonconformance: There is no management of judgment records. <Sample answers> • Test piece analysis report (for plating process)		(3) Enter the name of the record which contains the management result.		
39	Process Control	Verification of Documentation		++	++	(4) Do you have any document which defines the procedure to implement the management in (2) to (3) above?	<Conformance judgment criteria> Conformance: The procedure has been documented. Partial conformance: There are some deficiencies. Nonconformance: It has not been documented. <Sample answers> • "Process management regulations" Item No. XX: Management of conversion process "Operation Procedure"		(4) Enter the names of the documents and the items defining the process management.		
5.5.5.2 Prevention of incorrect use and contamination (Management of incorrect use and contamination for parallel production and prohibited substances)											
The organization shall implement preventative measures against incorrect use and contamination for the chemical substances subject to the CiP management criteria.											
40	Process Control	Verification of Implementation	++		++	(1) Do you implement preventative measures against incorrect use and contamination for the chemical substances subject to the CiP management criteria? * Actions for the "prohibited substances" specified in the CiP management criteria are verified in (2) to (6).	<Conformance judgment criteria> Conformance: The chemicals requiring measures to prevent mistaken use and contamination and the management methods are defined and implemented. Nonconformance: There is no appropriate management or implementation. <Sample answers> • The management is practiced in accordance with a QC process chart. <Points to note in management> • It is acceptable if the details of measures to prevent mistaken use and contamination are specified according to the management level of the chemical substances that may cause contamination (prohibited substance or management of contained substances). • If there is no possibility of the incorrect use of or contamination with "prohibited substances" as defined by the CiP management criteria, it is acceptable if the company conducts general process control to prevent incorrect use and contamination. • If there is a process or a material that has a risk of the incorrect use of or contamination with "prohibited substances" as defined by the CiP management criteria, the company needs to undertake actions (3) to (6) below.		(1) Enter an outline and overall image of the management method. * Write details in (3) to (6) on the specific management method for a process which may lead to the incorrect use of or contamination with a "prohibited substance" as defined in the CiP management criteria.		
41	Process Control	Verification of Implementation	--	--	++	<Actions for prohibited substances> (2) Is there any process or material for which there is a risk of the incorrect use of or contamination with a "prohibited substance" as specified in the CiP management criteria, or any process or material for which this has not yet been verified? *If there is no risk of contamination or incorrect use and also there are no processes or materials for which this has not been verified, then enter "non-applicable" in (3) to (6).	<Sample answers> • Parts or material: Electrical cable • Prohibited substances: Lead • Process: Surface mount process • Use: To be used for automobile parts <Points to note in management> • The company needs to include not only the processes for the targeted customer, but also other processes when judging whether or not there is a risk of the incorrect use of or contamination with a "prohibited substance." • The following are examples of cases where there is a risk of the incorrect use of or contamination with "prohibited substances" as defined by the CiP management criteria. Example: There is parallel production using "prohibited substances" in a production line allocated to a customer excluded from restrictions. Example: Recycled material (open / closed) is used.		(2) If there are parts or materials containing prohibited substances, list the names of the parts and materials containing prohibited substances, the names of the prohibited substances, the processes and the purposes of the use.		
42	Process Control	Verification of Implementation	++		++	<Actions for prohibited substances> (3) Do you conduct proper management to prevent incorrect use and contamination at the receiving of parts and materials and in the storage area (including secondary materials and packing materials)?	<Conformance judgment criteria> Conformance: Appropriate management is implemented to prevent incorrect use and contamination at the receiving of parts and materials and in the storage area. * For the appropriateness, judgments of the necessity of implementation, the details of evidence and the frequency, etc., should be made individually based on the industry type, target processes and materials, etc. Nonconformance: There is no appropriate management implemented. <Sample answers (Management method)> • A "Nonconforming" label is attached to nonconforming parts (electrical cable containing lead) at receiving. • A divider is placed in the storage area to segregate nonconforming parts and materials that contain prohibited substances. • At receiving, the company uses tools such as XRF analysis equipment and GC/MS analysis equipment to analyze each lot of open recycled materials to verify that prohibited substances do not exceed the threshold value due to inconsistency of concentration. <Points to note in management> • To be an effective management method to prevent incorrect use and mixing in, the management method has to be such that no mistakes will be made whoever performs the work, with measures such as labeling, dedicated use and limiting the people in charge.		(3) Enter the specific method of management to prevent incorrect use, mixing in and contamination at the "parts and material storage area (including secondary material and packing material)."		
43	Process Control	Verification of Implementation	++		++	<Actions for prohibited substances> (4) Do you conduct proper management to prevent incorrect use and contamination in all of the relevant manufacturing processes below? (a) Line processes (including peripherals) (b) Work-in-progress storage (including the long-term WIP storage area) (c) Rework processes (e.g. a correction process for soldering that is not a normal production line process) (d) Production equipment, tools and jigs (if they touch or attach to parts or materials)	<Conformance judgment criteria> Conformance: Appropriate management is implemented to prevent incorrect use and contamination in the relevant manufacturing processes in (a), (b), (c) and (d). * For the appropriateness, judgments of the necessity of implementation, the details of evidence and the frequency, etc., should be made individually based on the industry type, target processes and materials, etc. Nonconformance: There is no appropriate management implemented. <Sample answers (Management method)> (a) Line processes (including peripherals) • The company designates a line using a "prohibited substance" (a line designated for a customer with no restrictions) as being for exclusive use and puts up a sign for identification. • Solder irons and the cleaning sponges for them are designated for exclusive use and an identification sticker is attached to them. (b) Work-in-progress storage (including the long-term WIP storage area) • The company allocates a special area to store WIP which is not subject to restrictions for "prohibited substances" and puts up a sign for identification. • The company keeps long term WIP in a locked area and limits the people in charge of its handling. (c) Rework process • The company designates a special repair line for reworking which is not subject to restrictions for "prohibited substances." (d) Production equipment, tools and jigs (if they touch or attach to parts or materials) • The company dedicates production equipment, tools and jigs for use when there are no restrictions for "prohibited substances" and attaches a label for identification (sticker). • The company defines the cleaning standards for production equipment, tools and jigs which are used when there are no restrictions for "prohibited substances" and conducts the management accordingly. <Points to note in management> • To be an effective management method to prevent incorrect use and contamination, the management method has to be such that no mistakes will be made whoever performs the work, with measures such as labeling, dedicated use and limiting the people in charge for contamination.		(4) Enter the specific management method to prevent incorrect use, mixing in and contamination in the following manufacturing processes. (a) Line processes (including peripherals) [(b) Work-in-progress storage (including the long-term WIP storage area) [(c) Rework process [(d) Production equipment, tools and jigs (if they touch or attach to parts or materials) [		
44	Process Control	Verification of Implementation	++		++	<Actions for prohibited substances> (5) Do you conduct proper management to prevent incorrect use and contamination where the products are stored in the warehouse for shipping?	<Conformance judgment criteria> • Conformance: Appropriate management is implemented to prevent incorrect use and contamination in the shipping warehouse. * For the appropriateness, judgments of the necessity of implementation, the details of evidence and the frequency, etc., should be made individually based on the industry type, target processes and materials, etc. Nonconformance: There is no appropriate management implemented. <Sample answer (Management method)> • The company puts a sign on products or packaging (label, etc.) for identification and allocates a special storage area. <Points to note in management> • To be an effective management method to prevent incorrect use and contamination, the management method has to be such that no mistakes will be made whoever performs the work, with measures such as labeling, dedicated use and limiting the people in charge.		(5) Enter the specific management method to prevent incorrect use, mixing in and contamination in the "product storage in the shipping warehouse."		
45	Process Control	Verification of Documentation		++	++	<Actions for prohibited substances> (6) Do you have any document which defines the procedure to implement the management in (3) to (5) above?	<Conformance judgment criteria> Conformance: The appropriate management method to prevent incorrect use and contamination is documented. Nonconformance: It has not been documented. <Sample answers> • "Process management regulations" Item No. XX: Management of prohibited substances - The procedure of production switching		(6) Enter the names of the documents and the items defining the management procedure to prevent incorrect use, mixing in and contamination in the applicable processes.		
5.5.5.3 Identification and traceability											
The organization shall take appropriate measures to secure the traceability of CiP information so that it can grasp the CiP information and quickly use, disclose and communicate that information. The organization shall define, save and implement the management method for CiP information related to products.											
46	Common management	Verification of Implementation and Recording	++		++	From a product that is delivered, are you able to quickly grasp, utilize, disclose and transfer the receiving lot of components/parts/raw materials, the manufacturing time and manufacturing processes and the outsourcing organization CiP information? (a) The management method is defined (b) A record is created	<Conformance judgment criteria> Conformance: The procedures and records concerned are defined and the operation is verified. Partial conformance: There are deficiencies in the records. Nonconformance: The management method is not defined. Or else, there are no records. <Sample answers> (a) • "Process management regulations" Item No. XX: Traceability • "Manufacturing management regulations" Item No. XX: Traceability "Work procedure" • Managed using lot numbers or serial numbers. (b) • Parts receiving records • Lot management record • Production record <Points to note in management> • If it is difficult to write the detailed management method, then it is acceptable to write the name of the procedure document.		Enter the management method and record used to identify the receiving lot of components/parts/raw materials, the manufacturing time, the manufacturing location (processes) and the outsourcing organization from the delivered products. (a) Document name/Management method outline: [[(b) Record: [		

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

Action Items (Details)

No	Item Classification	Bio-Classification	Question Flag: Basic	Question Flag: Advanced *Select	Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization: Self-Evaluation Result	by Self-Evaluating Organization: Answer (Implementation details, evidence name, etc.)	by Evaluation-Result Verifying Organization: Judgment Result	by Evaluation-Result Verifying Organization: Judgment reason, memo, remarks, etc.
5.5.6 Change management										
	The organization shall extract change elements which may affect the chemical substances subject to the CiP management criteria. Before a change is made, the organization shall first conduct appropriate checks for any change in the CiP and conduct a review using the CiP management criteria. **The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.**									
47	Common management	Verification of Implementation	++	++	(1) Have you defined the items subject to change management?	<Conformance judgment criteria> Conformance: The items subject to change management have been stated explicitly. Partial conformance: There is no explicit definition, but it is possible to give examples that are subject to change management. Nonconformance: The items subject to change management are not defined. <Sample answers> (a) Items subject to change management: The following are subject to change management in the organization internally, at the supplier and at the outsourcing organization. Supplier, outsourcing organization Part, material Process (Production equipment, manufacturing condition, mold/die, tools and jigs, etc.) (b) Document name: Change management regulations <Points to note in management> • The 4 elements of production of "Man," "Machine," "Material" and "Method" are included in change management. However, only to the extent that affects chemical substance management. • Changes subject to change management must include not only changes in the organization internally, but also any change made at the supplier or the outsourcing organization.		(1) List the items which are subject to change management and the document names. (a) Change management subject: [(b) Name of Document: [		
48	Common management	Verification of Implementation	++	++	(2) For cases when there is an item that is subject to the change management in (1), are there clear definitions of the department (person), timing and method for the acquisition of the necessary CiP information after checking the necessity before the change is made?	<Conformance judgment criteria> Conformance: There are clear definitions of the timing, method and department (person) for the acquisition of the necessary CiP information at the time of change management and also the acquisition is implemented before the change is made. Partial conformance: The information is acquired, but the method or the department (person) is not defined. Nonconformance: The information is not acquired, or the information is not acquired before the change is made. <Sample answers> • The purchasing department uses the CiP information (chemSHERPA, JAMA/JAPIA sheet, etc.) to obtain the information from the supplier before the change is made. • The purchasing department uses the certificate of non-use or composition table to obtain the information from the supplier before the change is made. <Points to note in management> • Check whether or not information is acquired that makes it possible to judge whether there is conformance or nonconformance to the management criteria.		(2) Enter the details verified to understand the status of conformance to CiP management criteria before a change is made when a change arises to an item subject to change management in the organization internally as shown in (1). (a) Acquisition department: [(b) Acquisition timing: [(c) Acquisition method: [		
49	Common management	Verification of Implementation	++	++	(3) For cases when the subject of the change management in (1) above will affect a customer or the shipping of a product to a customer, are there clear definitions of the department (person), timing and method for reporting to the customer before the change is made?	<Conformance judgment criteria> Conformance: There are clear definitions of the timing, method and department (person) for the communication of changes to customers and also there is a record of the communication of changes. Nonconformance: The timing, method and department (person) for the communication of changes to customers are not defined. Or else, there is no record of changes being communicated. <Sample answers> • There is a system for the quality assurance department to notify customers in advance of the items to be changed (supplier, material, process, etc.) and the status of conformance with the CiP management criteria and applications are implemented using the change request form specified by each company. <Points to note in management> • It is important that a change should be made after communicating with the customer. • It is important to report to the customer about the status of conformance to the CiP management criteria no matter what the outcome is.		(3) Enter the timing and method of reporting to the customer before the change is made. (a) Reporting department: [(b) Reporting timing: [(c) Reporting method: [(d) Reporting record: [		
50	Common management	Verification of Recording	++	++	(4) For the CiP information obtained, do you judge the conformance status and record the results?	<Conformance judgment criteria> Conformance: There is a record of judgments. Nonconformance: There is no record of judgments. <Sample answers> (a) Judgment record: • In-house changes: The judgment result is written on the [Change application form (for in-house applications)]. • Supplier/outsourcing organization changes: The conformance status is written on the [Change application form (for supplier applications)]. (b) Person responsible for approval: Manager of quality control department <Points to note in management> • If approval is required for the judgment, there must be an approver and judgment record. • In cases when the change management requires a report to customers, there must be a judgment made regarding the conformance to the management criteria of the customer.		(4) Enter the name of the document in which results are recorded and the name of the approver of the judgment. (a) Judgment record: [(b) Person responsible for approval: [		
5.5.7 Delivery of products										
	Before the organization delivers products, the organization shall first check if the products satisfy the CiP management criteria for product deliveries. **The organization shall retain documented information on the delivery of products. This information shall include the following:** **a) Evidence of conformity with the CiP management criteria** **b) Traceability to the person(s) authorizing the delivery** **The organization shall also manage product warehouses to prevent incorrect shipment and contamination.** **The organization shall consider matters such as the laws, regulations and industry standards covered by the CiP management criteria, any nonconformance and the feedback from customers and shall also decide and implement the action to be taken after delivery for the products supplied.**									
51	Process Control	Verification of Implementation and Recording	++	++	Do you verify and record whether the "CiP management criteria" are satisfied at the delivery stage?	<Conformance judgment criteria> Conformance: There are stored records of verification that the CiP management criteria were satisfied. Partial conformance: There are deficiencies in the records. Nonconformance: No record is kept. <Sample answers> (a) Document name: "Shipping verification regulations" Item No. xxx: Evaluation of chemical substances in products (Shipping inspection document name/criteria, etc.) (b) Record: Shipping inspection tag, identification tag, process verification record, etc. <Points to note in management> • The delivery stage refers to the shipping of end products. • If there are separate rules for activities after shipping, then follow those rules.		Enter the procedure and record for verification of whether the "management criteria related to CiP management" are satisfied at the delivery stage? (a) Name of Document: [(b) Record: [		
5.5.8 Response to occurrence of nonconformity										
	The organization shall decide and document the methods to be used when nonconformity in CiP occurs, to quickly contact persons within the organization, suppliers, outsourcing organizations and customers and to take temporary corrective action. **After the temporary measure is taken, the organization shall investigate and identify the cause and determine and implement the necessary countermeasures to prevent recurrence.** **The organization shall take preventive measures to avoid any occurrence of nonconformity. The organization shall retain documented information on the action when a nonconforming product occurs.**									
52	Common management	Verification of Implementation	++	++	(1) Have you defined and do you implement procedures for contacting parties within the organization and at suppliers, outsourcing organizations and customers when there is an occurrence of nonconformity in CiP (hereinafter called a "non-conforming item")?	<Conformance judgment criteria> Conformance: The procedures for contacting parties within the organization and at suppliers, outsourcing organizations and customers are defined in a document. Partial conformance: The procedures above are defined in a document, but there are parts that are unclear. Nonconformance: There is no document defining the procedures that should be implemented. <Sample answers> (a)Procedure for contact from the supplier/the outsourcing organization: 1) Document name, item name: Green procurement criteria, Edition ** Item ** 2) Details requested: Details of nonconformance and information for the identification of the extent of impact. 3) Record name: Nonconformance occurrence report (b) In-house contacting procedure and the procedures to decide measures: 1) Document name, item name: CiP management regulations, Edition ** Item ** 2) Details requested: Same as in procedure 3) Record name: Problem occurrence report (c) Reporting procedure to the customer: 1) Document name, item name: CiP management regulations, Edition ** Item ** 2) Details requested: The initial report is made from the department of the occurrence to the quality assurance department and related departments and then the extent of the impact is identified and measures are taken to prevent expansion and also an initial report is sent to the customer. Provisional measures are implemented after discussion with the customer. After the cause is identified, permanent measures, preventative measures and the application of measures extensively are conducted in accordance with the regulations. 3) Record name: Problem occurrence report <Points to note in management> • There must also be the inclusion of a procedure for notification of nonconformance from the supplier/the outsourcing contractor.		(1) Enter the names of the documents requesting the reporting procedures below when nonconformity occurs and the details that are requested. (a)Procedure for contact from the supplier/the outsourcing organization: 1) Name of document, name of item: [2) Details requested: [3) Record name: [(b) In-house contacting procedure and the procedures to decide measures: 1) Name of document, name of item: [2) Details requested: [3) Record name: [(c) Reporting procedure to the customer: 1) Name of document, name of item: [2) Details requested: [3) Record name: [		
53	Common management	Verification of Implementation	++	++	(2) Have you defined and do you implement procedures for temporary action when a non-conforming item occurs, to identify the extent of the impact, prevent expansion and identify and manage items?	<Conformance judgment criteria> Conformance: The details that should be implemented are defined in a document. Partial conformance: The details that should be implemented are defined, but some parts are unclear. Nonconformance: There is no document defining the details that should be implemented. <Sample answers> (a) Identification of area of influence 1) Document name, item name: Corrective action procedure, Item ** Emergency action 2) Details requested: Identification of lot(s) where occurred and the equipment affected 3) Record name: Corrective action record (b) Prevention of expansion 1) Document name, item name: Corrective action procedure, Item ** Emergency action 2) Details requested: Suspension of production, suspension of shipping, sorting/isolation, etc. 3) Record name: Corrective action record (c) Identification management 1) Document name, item name: Corrective action procedure, Item ** Emergency action 2) Details requested: Isolation from conforming items and attachment of identification indication 3) Record name: Corrective action record		(2) Enter the names of the documents to prevent expansion and conduct identification management when nonconformity occurs and enter the details requested. (a) Identification of area of influence 1) Name of document, name of item: [2) Details requested: [3) Record name: [(b) Prevention of expansion 1) Name of document, name of item: [2) Details requested: [3) Record name: [(c) Identification management 1) Name of document, name of item: [2) Details requested: [3) Record name: [		
54	Common management	Verification of Implementation	++	++	(3) Have you defined and do you implement procedures to investigate the cause and implement permanent measures and/or preventative measures for that cause?	<Conformance judgment criteria> Conformance: There is a procedure defined for when nonconformance in CiP occurs, including for the methods to determine the cause, revise criteria and report in the company and to customers, and there are implementation records remaining. Partial conformance: There are deficiencies in the procedures and records. Nonconformance: There are no records. <Sample answers> (a) Document name, item name: Product nonconformity notification sheet/report (b) Details requested: The manufacturing department investigates the cause and implements permanent countermeasures and preventative measures and then contacts the quality assurance section. (c) Record name: As above <Points to note in management> • The company has established the procedure to take corrective actions against the cause of nonconformance or measures to prevent recurrence such as revising the criteria.		(3) Enter the contents specifying a cause investigation, countermeasure and preventive measures. (a) Name of document, name of item: [(b) Details requested: [(c) Record name: [		
55	Common management	Verification of Implementation	++	++	(4) Have you defined and do you implement procedures to apply recurrence prevention measures extensively?	<Conformance judgment criteria> Conformance: For the prevention of problem recurrence and preventative action, the procedure for the consideration of extension to other processes and products is defined in a document. Partial conformance: There are some deficiencies in the procedures and records. Nonconformance: There are no procedures or records. <Sample answers> (a) Document name, item name: Product nonconformity notification sheet/report (b) Details requested: Based on the information obtained, the quality assurance section considers the necessity for extension throughout the organization and to departments and processes other than where the problem occurred and if necessary implements it. (c) Record name: As above		(4) Enter the contents specifying the extensive implementation of measures to prevent recurrence. (a) Name of document, name of item: [(b) Details requested: [(c) Record name: [		

Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

Action Items (Details)

No	Item Classification	Sub-Classification	Question Flag: Basic	Question Flag: Advanced +Select	Questions	Conformance judgment criteria, sample answer, points to note in management	by Self-Evaluating Organization: Self-Evaluation Result	by Self-Evaluating Organization: Answer (Implementation details, evidence name, etc.)	by Evaluation-Result Verifying Organization: Judgment Result	by Evaluation-Result Verifying Organization: Judgment reason, memo, remarks, etc.
5.6 Performance evaluation and improvement										
					The organization shall evaluate the following items at predetermined intervals. The organization shall implement corrective action for matters which require correction. The organization shall retain the results of evaluations and corrective action as documented information and shall report the results to top management. The top management shall review those results of evaluations and corrective action. **a) Situation of improvements** **b) Changes in external and internal issues related to CiP management** **c) Information on CiP management performance and effectiveness, including regarding the following trends:** **1) Relevant communication with external stakeholders** **2) Level of target achievement** **3) Conformance of products to CiP management criteria** **4) Nonconformity and corrective action** **5) Performance evaluation results** **6) Supplier and external outsourcing contractor performance** **d) Suitability of resources** **e) Effectiveness of actions to address risks and opportunities** **f) Improvement planning**					
56	Common management	Verification of implementation	++	++	(1) Do you evaluate the CiP management status periodically at a predetermined frequency?	<Conformance judgment criteria> Conformance: The frequency of verification and the method and means for verification are decided and there are records of verifications performed according to those rules. Partial conformance: There are some deficiencies in the methods and records. Nonconformance: There are no records. <Sample answers> (a) Verification frequency: Once a year (b) Verification method: Internal audit of CiP management (c) Record name: Internal audit record <Points to note in management> • There are cases when internal audits are implemented with CiP management incorporated into ISO9001 or ISO14001. In such cases, it is desirable that it is clearly stated in the procedure, records and audit scope, etc., that CiP management is included.		(1) Enter the frequency of the verification of the CiP management status and the verification method. (a) Verification frequency: [(b) Verification method: [(c) Record name: [		
57	Common management	Verification of implementation	++	++	(2) When the result of the evaluation in (1) is that correction is necessary, do you implement corrective action?	<Conformance judgment criteria> Conformance: There is a procedure defined for when nonconformance in CiP management occurs, including for the methods to determine the cause, revise criteria and report in the company and to customers, and there are implementation records. Partial conformance: There are some deficiencies in the procedures and records. Nonconformance: There are no records. <Sample answers> • Corrective action report		(2) Enter the name of the record which shows the implementation of necessary corrective actions.		
58	Common management	Verification of implementation	++	++	(3) Do the top management conduct reviews of the appropriateness and effectiveness of initiatives such as the results of evaluations and the results of corrective action?	<Conformance judgment criteria> Conformance: The procedures for top management for CiP management related evaluation results and corrective action are defined and records are kept. Partial conformance: There are some deficiencies in the procedures and records. Nonconformance: There are no records. <Sample answers> • Management review report <Points to note in management> • If the company implements internal audits with details incorporated into ISO9001, ISO14001 or others, it is advisable that the fact that the audit is also being implemented for CiP is stated in the "scope of audit" in the internal audit report.		(3) Enter the name of the record which shows the results of reviews by the top management of the CiP management.		
59	Common management	Verification of Documentation		++	(4) Do you have any documents that define the procedures to implement items (1) to (3) above?	<Conformance judgment criteria> Conformance: All the documents containing the systems and procedures to implement (1) to (3) above have been prepared. Partial conformance: There are some parts that are insufficient. Nonconformance: Only half or less of the documents have been prepared. <Sample answers> • "Internal audit regulations" • "CiP management regulations" Item no. xx: Management review		(4) Enter the names of the documents and the items specifying the evaluation of the implementation status and the implementation of improvements.		

Annex F：Self-Declaration of Conformance

The following is the sample format of Self-Declaration of Conformance with the data entry example and explanation

The sample of Self-Declaration of Conformance is provided in Microsoft Word format.

Self-Declaration of Conformance (sample of form and entries (partial))

Self-Declaration of Conformance based on Guidelines for the Management of Chemicals in Products

1. Number : .....

2. Issuer： .....
   Address of Issuer： .....

3. Subject of Declaration : .....

4. The above declaration complies with requirements specified in the documents below:
   Name of Document: Guidelines for the management of chemicals in products
   Edition: Edition 4.0
   Date of Issue: March 2018
   Issuer: Joint Article Management Promotion-consortium JAMP

5. Additional information
   Verification method: Conformance was verified based on the result of the self-audit (conducted in the month of xxx 2018) using the Check Sheet (Ver. 4.01).
   Other: Conformance with all relevant basic level questions

6. Signature of Representative
   Name: .....
   Job title: .....
   Place of issue: .....
   Signature

7. Date and Place of Issue
   Date of Issue: (day) (month) (year)
   Date of update: (day) (month) (year) (optional)

8. For any enquiry about the declaration of conformance, please contact below:
   Name: .....
   Department: .....
   E-mail: .....
   Telephone: .....

Example of Data Entry of Self-Declaration of Conformance and Explanation

■ Note indicates data entry is compulsory, whereas □Note shows optional data entry.

1. Number

■ Note 1 The organization issuing the Self-Declaration of Conformance shall state an identification code as a reference number in case of any enquiry received internally or externally. The identification code may include characters other than numerical figures.

(Example 1-1) xxxx-2018-01

2. Name of Issuer / Address of Issuer

■ Note 2 Enter the name of the organization issuing a Self-Declaration of Conformance. For example, an issuer can be entered as shown below. In case that entry data takes too many lines, data can be entered using an attached sheet.

A. In case of only a specific organization in the company issuing the Self-Declaration of Conformance

(Example 2-1) xxxx Co. Ltd., xxxx Factory
12-3 xx-machi, xx City, Osaka Prefecture, Japan

(Example 2-2) xxxx Co. Ltd., xxxx Division
12-3 xx-machi, xx City, Osaka Prefecture, Japan

(Example 2-3) xxxx Co. Ltd., xxxx Factory, xxxx Division
12-3 xx-machi, xx City, Osaka Prefecture, Japan

B. In case that the Self-Declaration of Conformance is issued by multiple organizations, group companies or by the organization together with external outsourcing organizations. For self-declaration, the issuer can include an outsourcing organization without any capital tie or any share held by the issuer.

(Example 2-4) xxxx Co. Ltd., xxxx Factory
12-3 xx-machi, xx City, Osaka Prefecture, Japan
xxxx Co. Ltd., xxxx Factory
12-3 xxxx Town, xxxx County, Shizuoka Prefecture, Japan
Tohoku xxxx Co. Ltd., xxxx Factory
12-3 xx City, Aomori Prefecture, Japan
China xxxx Co. Ltd.
No. 1234-56 Dalian, Liaoning Province, People's Republic of China

C. In case of only a specific organization in the company issuing the Self-Declaration of Conformance

(Example 2-5) xxxx Co. Ltd., xxxx Factory
12-3 xx-machi, xx City, Ibaraki Prefecture, Japan

3. Subject of Declaration

■ Note 3 Enter the management system subject to Self-Declaration of Conformance. If the entry data takes too many lines, data can be entered using an attached sheet.

(Example 3-1) The company-wide management system of chemicals in products

(Example 3-2) The management system of chemicals in XXX products for xxxx use

(Example 3-3) The management system of chemicals at development, manufacturing and sales of xxxx products for xxxx use

(Example 3-4) The management system of chemicals in products for development, manufacturing and sales of electronics parts and components

4. The above declaration complies with requirements specified in the documents below.
[Specified requirements]

■ Note 4 Enter the name of referred documents, edition, the date of issue and the issuer as per the sample below.

(Example 4-1) Name of Document: Guidelines for the management of chemicals in products
Edition: Edition 4.0
Date of issue: March 2018
Issuer: Joint Article Management Promotion-consortium JAMP

5. Additional information

□ Note 5(1) Enter information that is a base for the declaration of conformance such as the evaluation method of the organization. When the Check Sheet is used, the version number should be also provided.

(Example 5-1) Verification method: Conformance was verified based on the result of internal audit (conducted in the month of xxx 2018) using the Check Sheet (Ver. 4.01).

(Example 5-2) Verification Method: Conformance at our company was verified based on the result of a second-party audit (conducted in the month of xxx 2018).

6. Signature of Representative

■ Note 6 List the name of the representative, his/her department, job title and signature.
Depending on the size of the organization, the management system, the organization shall appoint the appropriate representative such as the president, senior director in charge, executive officer in charge or head of the department in charge.

(Example 6-1) Name: xxxx
Job title : Executive director in charge

Signature

7. Date and Place of Issue

■ Note 7 The place shall be where “the representative” is located. Enter the place again even if it’s the same as “2. Address of Issuer”.
Date of Issue represents the date when Self-Declaration of Conformance is issued for the first time. Renewal date may also be listed if it is necessary to show that conformance is ongoing based on the result of a periodic internal audit.

(Example 7-1) Name: xxxx
Place: 1-2-3 xxx, xxxx-ku, Tokyo, Japan
Date of Issue: xx (day) xx (month) 2018
Date of update: xx (day) xx (month) 2018 (optional)

8. For any enquiry about the declaration of conformance, please contact below:

■ Note 8(1) The issuer may list both the representative of the organization and the person in charge of operation (contact person).
The issuer may provide the telephone number or email address.

(Example 8-1) Name: xxxx
Department: Head Office xxxx Division, xxx Promotion Section
Telephone: 06-xxxx-xxxx
E-mail: abcde-fghijklm@xyzxyz.co.jp

□ Note 8(2) The organization may prepare support documents for the Self-Declaration of Conformance to provide details of the declaration.
If the organization declares conformance with other requirements in addition to conformance with these Guidelines, the organization shall state this in support documents. However, it is not necessary to disclose support documents together with the Self-Declaration of Conformance.

Revision History

27 Sept 2005	Guidelines for the Management of Chemicals in Product Ver. 1 Newly issued based on the Japan Green Procurement Survey Standardization Initiative (JGPSSI)
07 Nov 2006	Guidelines for the Management of Chemicals in Product Ver. 1.1 Revised by JGPSSI (correction of errors in text and addition of some sectional explanation, etc.)
02 July 2007	Guidelines for the Management of Chemicals in Products Ver. 1 Published by the Joint Article Management Promotion-consortium (JAMP) (members only)
31 Mar 2008	Guidelines for the Management of Chemicals in Product Ver. 2 (Version 2 published by both JGPSSI and JAMP as the outcome of joint efforts)
20 Feb 2013	Guidelines for the Management of Chemicals in Products Ver. 3.0 Ver. 3.0 published as the joint study of "Collaboration Committee of Guidelines for the Management of Chemical Substances in Products Ver. 3.0." (Japan Chemical Industry Association (JCIA), The Japan Iron and Steel Federation (JISF), Japan Surface Finishing Suppliers Federation (KZK), Four Electrical and Electronic Organizations (JEMA, JEITA, CIAJ and JBMIA), the Expert Committee on Chemical Substances in Products, JGPSSI, JAMP) Compliance with JIS Z 7201:2012
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Members of Collaboration Committee of Guidelines for the Management of Chemicals in Products Ed. 4

Japan Surface Finishing Suppliers Association (KZK)
Japan Ship Machinery and Equipment Association (JSMEA)
Japan Adhesive Tape Manufacturers' Association (JATMA)
Nippon Electric Control Equipment Industries Association (NECA)
The Japan Iron and Steel Federation (JISF)
The Japanese Electric Wire & Cable Makers' Association (JCMA)
Japan Chemical Industry Association (JCIA)
Japan Aluminium Association (JAA)
Japan Electronics and Information Technology Industries Association (JEITA)
National Federation of Small Business Associations (NFSBA)
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1 Mar 2018

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