Guidelines for the management of chemicals in products (CiP)

Edition 4.0

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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 verifies the supplier’s 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.

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.
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

<table>
<thead>
<tr>
<th>Management of chemicals in products</th>
<th>JIS Z 7201:2017 Management of Chemicals in Products – Principles and Guidelines</th>
</tr>
</thead>
</table>

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.

<table>
<thead>
<tr>
<th>Terms</th>
<th>Definition (underlined are defined terms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical substance</td>
<td>A chemical element or compound that either exists in nature or is obtained through a manufacturing process.</td>
</tr>
<tr>
<td>Mixture</td>
<td>A mixture intentionally comprising two or more chemical substances Note: Examples are paints, inks, alloy ingot, solder, resin pellets containing additives, etc.</td>
</tr>
<tr>
<td>Chemicals</td>
<td>Chemical substance or mixture.</td>
</tr>
<tr>
<td>Article</td>
<td>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.</td>
</tr>
<tr>
<td>Part</td>
<td>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. Note: 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. Note: 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</td>
</tr>
<tr>
<td>End product</td>
<td>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. Note: Personal computer: a personal computer – Electronics device: a telephone set – Transport equipment: an automobile – Machine tool: an electric drill – Furniture: a bed</td>
</tr>
<tr>
<td>Product</td>
<td>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.</td>
</tr>
<tr>
<td>Organization</td>
<td>Group with its own functions involving responsibility, authority and interrelationships.</td>
</tr>
<tr>
<td>Supplier</td>
<td>An organization which delivers products to the downstream.</td>
</tr>
<tr>
<td>Terms</td>
<td>Definition (underlined are defined terms)</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 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.

<table>
<thead>
<tr>
<th>Terms</th>
<th>Definition (underlined are defined terms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conformity</td>
<td>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.</td>
</tr>
<tr>
<td>Nonconformity</td>
<td>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.</td>
</tr>
<tr>
<td>Parallel production</td>
<td>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.</td>
</tr>
<tr>
<td>Outsourcing organization</td>
<td>External organization which is assigned to undertake all or a part of operations or functions of the organization.</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Stage</th>
<th>Action Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design and development</td>
<td>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.</td>
</tr>
<tr>
<td>Purchasing</td>
<td>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.</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>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.</td>
</tr>
<tr>
<td>delivery</td>
<td>The organization shall verify that products to be delivered should satisfy the management criteria of chemicals in products.</td>
</tr>
</tbody>
</table>

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 advises carrying out management of chemicals in products in cooperation with the organization which holds relevant knowledge and experiences.

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

<table>
<thead>
<tr>
<th>Conversion process</th>
<th>Chemical product to be used</th>
<th>Material to be processed (article)</th>
<th>New article</th>
<th>Phenomenon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Painting</td>
<td>Paint Ink</td>
<td>Base material</td>
<td>Painted base material Ink printed product</td>
<td>Volatilization: Some or all components of original chemical substances contained in a chemical product are removed by evaporation (subtraction processing)</td>
</tr>
<tr>
<td>Printing</td>
<td>Glass paste</td>
<td>Base material</td>
<td>Pattern-formed glass substrate</td>
<td></td>
</tr>
<tr>
<td>Synthetic adhesion</td>
<td>Adhesive</td>
<td>Base material</td>
<td>Plywood</td>
<td></td>
</tr>
<tr>
<td>UV printing</td>
<td>UV ink</td>
<td>Base material</td>
<td>UV-ink printed product</td>
<td></td>
</tr>
<tr>
<td>Epoxy sealing</td>
<td>Epoxy resin</td>
<td>Sealed chip</td>
<td>Sealed semiconductor chip</td>
<td></td>
</tr>
<tr>
<td>Plating</td>
<td>Plating fluid</td>
<td>Base material</td>
<td>Plated Base material</td>
<td></td>
</tr>
<tr>
<td>Plastic molding</td>
<td>ABS pellet</td>
<td>-</td>
<td>ABS plastic casing</td>
<td></td>
</tr>
<tr>
<td>Soldering</td>
<td>Solder</td>
<td>Mounted substrate</td>
<td>Soldered mounted substrate</td>
<td></td>
</tr>
<tr>
<td>Die casting</td>
<td>Alloy ingot</td>
<td>-</td>
<td>Die-cast part</td>
<td></td>
</tr>
</tbody>
</table>

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).
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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).

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.
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.

<table>
<thead>
<tr>
<th>Action Items</th>
<th>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”</th>
</tr>
</thead>
</table>

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 fulfill 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
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 fulfill 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 effective 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 antitrust 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.
(6) 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...
(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

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
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</table>
                  - 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>
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<tr>
<th>Judgment</th>
<th>Criteria</th>
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<tbody>
<tr>
<td><strong>Conformity</strong></td>
<td>- 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.</td>
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<tr>
<td><strong>Partial conformance</strong></td>
<td>- 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.</td>
</tr>
<tr>
<td><strong>Nonconformity</strong></td>
<td>- 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.</td>
</tr>
<tr>
<td><strong>Non applicable</strong></td>
<td>- 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.</td>
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</table>

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>
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<tr>
<th>Comprehensive judging criteria</th>
<th>- Cases where all evaluations of applicable questions among the basic questions provided for each “action item” are “Conformance”</th>
</tr>
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(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

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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.

![Image of parallel production]

- **If not applicable as Parallel Production of restricted chemical substances, the handling of chemical substances subject to restriction in all processes shall be carried out in a separate building**

  - Receiving warehouse, WIP warehouse, end product-delivery in the same building

- **If applicable as Parallel Production of restricted chemical substances, receiving check is in the same building**

  - Manufacturing is in the same building

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**

<table>
<thead>
<tr>
<th>Management Framework</th>
<th>Corresponding action items and notes, etc.</th>
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<tbody>
<tr>
<td>I Purchasing chemical product</td>
<td>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)</td>
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<tr>
<td></td>
<td>5.5.4.1 Collection and Verification of Information of Chemicals in Products</td>
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<td>5.5.4.2 Verification of the Management Status of Chemicals in Products at Supplier</td>
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<td>5.5.4.3 Management of Chemicals in Products at Receiving</td>
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<tr>
<td>II Manufacturing chemical product</td>
<td>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)</td>
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<td>5.5.5.1 Management in the manufacturing process</td>
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<td>5.5.5.2 Prevention of Incorrect Use and Contamination</td>
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<td>4.5 Conversion Process to Article</td>
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<tr>
<td>III Delivery of chemical product</td>
<td>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)</td>
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<td>5.5.7 Delivery of products</td>
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<tr>
<td>IV Purchasing article</td>
<td>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)</td>
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<td>5.5.4.1 Collection and Verification of Information of Chemicals in Products</td>
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<td>5.5.4.2 Verification of the Management Status of Chemicals in Products at Supplier</td>
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<td>5.5.4.3 Management of Chemicals in Products at Receiving</td>
</tr>
<tr>
<td>V Manufacturing article</td>
<td>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)</td>
</tr>
<tr>
<td>Management Framework</td>
<td>Corresponding action items and notes, etc.</td>
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</tbody>
</table>
| VI Delivery of article | 5.5.5.1 Management in the manufacturing process  
5.5.5.2 Prevention of Incorrect Use and Contamination |
|                       | 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.

<table>
<thead>
<tr>
<th>Action Items</th>
<th>Check Sheet questions</th>
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<tbody>
<tr>
<td>5.1 Context of the organization</td>
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<tr>
<td>5.1.1 Understanding the organization and its context</td>
<td>Reference</td>
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<tr>
<td>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.</td>
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<tr>
<td>5.1.2 Understanding the needs and expectations of stakeholders</td>
<td>Reference</td>
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<tr>
<td>The organization shall clarify the following items to understand the needs and expectations of stakeholders.</td>
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<tr>
<td>a) The stakeholders closely related to the management of chemicals in products</td>
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<td>b) The requirements of those stakeholders that are closely related to the management of chemicals in products</td>
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<tr>
<td>5.1.3 Determining the Scope of Application of Management of Chemicals in Products</td>
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<tr>
<td>The organization shall determine the appropriate scope of application of management of chemicals in products.</td>
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<tr>
<td>When determining this scope, the organization shall consider:</td>
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<tr>
<td>a) The external and internal issues for the organization defined in 5.1.1</td>
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<tr>
<td>b) The requirements of stakeholders defined in 5.1.2</td>
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<tr>
<td>c) The relationship between the organization and chemical substances</td>
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<tr>
<td>d) The externally provided products handled by the organization and the products delivered to external parties</td>
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<tr>
<td>The scope of application of management of chemicals in products shall be put in a state that can be used as documented information.</td>
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<tr>
<td>5.1.4 Implementation of the Management of Chemicals in Products</td>
<td>Reference</td>
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<tr>
<td>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.</td>
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<tr>
<td>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.</td>
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<td>5.2 Leadership</td>
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<td>5.2.1 Leadership and commitment</td>
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<td>Top management shall demonstrate leadership and commitment with respect to the management of chemicals in products by.</td>
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<tr>
<td>a) Taking accountability for the effectiveness of the management of chemicals in products.</td>
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<tr>
<td>b) Positioning the management of chemicals in products as an activity of the organization.</td>
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<tr>
<td>c) Making the necessary resources available for use (Refer to 5.4.1).</td>
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<tr>
<td>d) Ensuring compliance with the management criteria for chemicals in products.</td>
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<td>5.2.2 Policy</td>
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<tr>
<td>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.</td>
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<tr>
<td>5.2.3 Roles, responsibility and authority of an organization</td>
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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

#### 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.

- Make it possible for the management of chemicals in products to achieve the intended results.
- Enhance the desirable effects.
- Prevent or reduce the undesired effects.
- 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

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:

- 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
- Points of improvement from performance evaluation

### 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.

#### 5.4.2 Competence

The organization shall conduct the following items for competence.

- 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.
- Ensure that the persons involved in the management of chemicals in products have competence on the basis of appropriate education/training or experience.
- Retain documented information on the implementation of education and training.

#### 5.4.3 Awareness

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

- Management Policy of Chemicals in Products
- Objectives relating to the management of relevant chemicals in products?
- The risks related to their own work that require attention
- Their contribution to the effectiveness of the management of chemicals in products, including the benefits of improved performance.
- The meaning of not conforming with the principles and action items for the management of chemicals in products.
<table>
<thead>
<tr>
<th>Action Items</th>
<th>Check Sheet questions</th>
</tr>
</thead>
</table>
| 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 | |
| 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. | 2 |
| 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 | |
| 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. | 2 |
| 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 | 1 |
<p>| 5.5.3 Management of Chemicals in Products at Design and Development | |
| 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 | 1 |</p>
<table>
<thead>
<tr>
<th>Action Items</th>
<th>Check Sheet questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>5.5.4 Management of externally provided products</td>
<td></td>
</tr>
<tr>
<td><strong>5.5.4.1 Collection and Verification of Information of Chemicals in Products</strong></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>7</td>
</tr>
<tr>
<td>5.5.4.2 Verification of the Management Status of Chemicals in Products at Supplier</td>
<td></td>
</tr>
<tr>
<td>The organization shall 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.</td>
<td>10</td>
</tr>
<tr>
<td>5.5.4.3 Management of Chemicals in Products at Receiving</td>
<td></td>
</tr>
<tr>
<td>The organization shall 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.</td>
<td>2</td>
</tr>
<tr>
<td>5.5.4.4 Verification of the Management Status of Chemicals in Products at Outsourcing</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>3</td>
</tr>
<tr>
<td>5.5.5 Management of Chemicals in Products in Manufacturing and Storage</td>
<td></td>
</tr>
<tr>
<td><strong>5.5.5.1 Management in the manufacturing process</strong></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>4</td>
</tr>
<tr>
<td><strong>5.5.5.2 Prevention of Incorrect Use and Contamination</strong></td>
<td></td>
</tr>
<tr>
<td>The organization shall implement preventive measures against contamination and incorrect use of declarable chemicals under the management criteria of chemicals in products.</td>
<td>6</td>
</tr>
<tr>
<td><strong>5.5.5.3 Identification and traceability</strong></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>1</td>
</tr>
<tr>
<td>5.5.6 Change management</td>
<td></td>
</tr>
<tr>
<td>Action Items</td>
<td>Check Sheet questions</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>5.5.7 Delivery of products</td>
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</tbody>
</table>
| 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. | 1                     |
| 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)

### Evaluation Item

<table>
<thead>
<tr>
<th>Evaluation Item</th>
<th>Question level</th>
<th>No. of Questions</th>
<th>by Self-Evaluating Organization</th>
<th>by Evaluation-Result Verifying Organization</th>
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</thead>
<tbody>
<tr>
<td>5.1.3 Determining the scope of the CiP management</td>
<td>Advanced</td>
<td>1</td>
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<td></td>
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<tr>
<td>5.2.2 Policy</td>
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<tr>
<td>5.2.3 Roles, responsibility and authority of an organization</td>
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<tr>
<td>5.3.2 Objectives and planning to achieve them</td>
<td>Advanced</td>
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<tr>
<td>5.4.2 Competence</td>
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<td>5.4.5 Documented information</td>
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<tr>
<td>5.5.2.1 Customer communication</td>
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<tr>
<td>5.5.2.2 Defining the CiP management criteria</td>
<td>Advanced</td>
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<tr>
<td>5.5.3 CiP Management in design and development</td>
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<tr>
<td>5.5.4.1 CiP information collection and verification</td>
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<td>5</td>
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<tr>
<td>5.5.4.2 Verification of the CiP management status at suppliers</td>
<td>Advanced</td>
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<tr>
<td>5.5.4.3 CiP management at receiving</td>
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<tr>
<td>5.5.4.4 Verification of the CiP management status at outsourcing organization</td>
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<td>2</td>
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</tr>
<tr>
<td>5.5.5.1 Management in manufacturing processes (Management of conversion process)</td>
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<td>1</td>
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<tr>
<td>5.5.5.2 Prevention of incorrect use and contamination (Management of incorrect use and contamination for parallel production and prohibited substances)</td>
<td>Advanced</td>
<td>1</td>
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</tr>
<tr>
<td>5.5.3.3 Identification and traceability</td>
<td>Advanced</td>
<td>1</td>
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<tr>
<td>5.5.6 Change management</td>
<td>Advanced</td>
<td>4</td>
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<tr>
<td>5.5.7 Delivery of products</td>
<td>Advanced</td>
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<tr>
<td>5.5.8 Response to occurrence of nonconformity</td>
<td>Advanced</td>
<td>4</td>
<td></td>
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<tr>
<td>5.6 Performance evaluation and improvement</td>
<td>Advanced</td>
<td>3</td>
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<tr>
<td>Total</td>
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<td>13</td>
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</tbody>
</table>

### Final judgment

**<Company name>, <Department>, <Name> 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.**
5.1.1 Understanding the organization and its context

5.1.2 Understanding the needs and expectations of stakeholders

**Guidelines for the Management of Chemicals in Products (CiP) (Ver. 4.0)**

**Annex: Check Sheet (Var. 4.0)**

- **Company:** [Company Name]
- **Date of Self-evaluation:** [Date]

**Company Management System (CiP) Control System**

The guidelines or other documents referred to in the check sheets may contain the same content as the guidelines. These are specific descriptions of the items necessary to implement CP management appropriately and efficiently, based on the CiP Guidelines.

**Action Items**

- **References:** [Entry Requirement]
  - [Evaluation criteria, sample answer, Conformance judgment criteria]
  - [Points to note in management]

**Questions**

- **Confidence judgment criteria, sample answer, points to note in management**
- **Self-Evaluation Result**
- **Evaluation-Result verifying organization**

**[Final verification result] [Comment]**

- **Evaluation result score / No. of items:**
- **Select Evaluation Result**
- **Total:** 3

**Guidelines for the Management of Chemicals in Products (CiP) (Ver. 4.0)**

**Annex: Check Sheet (Var. 4.0)**

**[Click Sheet demonstrates "Chemicals in products" to CP] (CiP: Abbreviation of Chemicals in Products)**

<table>
<thead>
<tr>
<th>No.</th>
<th>Title</th>
<th>Questions</th>
<th>Conformance judgment criteria, sample answer, points to note in management</th>
<th>Self-Evaluation Result</th>
<th>Evaluation-Result verifying organization</th>
<th>[Final verification result] [Comment]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>a) Documented information name:</td>
<td></td>
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<tr>
<td>2</td>
<td>b) Outline</td>
<td></td>
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<tr>
<td>3</td>
<td>c) CiP management regulations</td>
<td></td>
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<tr>
<td>4</td>
<td>d) The externally provided products handled by the organization and the products delivered to external parties</td>
<td></td>
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</tr>
</tbody>
</table>

**[Click sheet]**

1. **Guidelines for the Management of Chemicals in Products (CiP) (Ver. 4.0)**
2. **Annex: Check Sheet (Var. 4.0)**
Policy

5.2.2 Policy

The top management shall establish the CiP management policy for the organization and shall formulate, implement and maintain plans based on that policy. Furthermore, the top management shall strive to continuously improve the CiP management.

5.2.3 Objectives and planning to achieve them

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

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) Enhance the desirable effects.
- c) Retain documented information on the implementation of education and training.

5.1.4 Implementation of CiP management

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.

5.3.1 Actions to address risks and opportunities

The organization shall address the risks and opportunities that must be approached as listed below to realize the intended results of the organization.

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.

5.3.2 Roles, responsibility and authority for the organization

The 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) Implementing the CiP management system as outlined in the guidelines.
- c) Retaining and communicating the management policy.

In order to ensure that the CiP management policy is understood, the organization shall communicate the policy to all personnel and obtain their commitment.

The organization shall establish, implement, maintain and continuously improve the CiP management system in accordance with the basic thinking and action items for CiP management stated in the Guidelines.

5.2.4 Verification of dissemination

The organization shall conduct the following items for verification of dissemination.

- a) Document declaring policy, etc.: The organization shall define the roles and responsibilities of the departments related to CiP management, their roles and the CiP management regulations. The organization shall be responsible for the release of the information to the departments concerned.
- b) The method of dissemination:
  - Document declaring policy, etc.: The method of dissemination is defined in the CiP management regulations or the implementation plan.
  - The roles and departments related to CiP management: The method of dissemination is defined in the CiP management regulations or the implementation plan.
- c) Dissemination of the roles in (a) and (b): The method of dissemination is defined in the CiP management regulations or the implementation plan.

5.2.5 Policy on education and training

The organization shall maintain the education and training of all personnel involved in CiP management, including the awareness of the organization’s management objectives and policies.

5.3.3 Actions to address these issues

The organization shall conduct the following items for actions to address these issues.

- a) Enter the name of the document for the education and training related to CiP management and the recording:
  - Training contents and records for main individual education and training:
    - (a) Name of document that defines the operation rules for education and training:
    - Contents of training:
    - Record:
    - Target staff:

5.2.3 Actions to address these issues

The organization shall conduct the following items for actions to address these issues.

- a) Enter the name of the document for the education and training related to CiP management and the recording:
  - Training contents and records for main individual education and training:
    - (a) Name of document that defines the operation rules for education and training:
    - Contents of training:
    - Record:
    - Target staff:

5.3.4 Actions to address these issues

The organization shall conduct the following items for actions to address these issues.

- a) Enter the name of the document for the education and training related to CiP management and the recording:
  - Training contents and records for main individual education and training:
    - (a) Name of document that defines the operation rules for education and training:
    - Contents of training:
    - Record:
    - Target staff:
### Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

#### 5.4.4 Communication

5.4.4.2 External communication

- 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.
- For the information necessary for CiP management, the organization shall establish and implement procedures related to communication between the various levels and functions (departments) of the organization.

5.5 Operation

- 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.
  - The acquisition of information on the laws, regulations and industry standards that the customer must comply with.
  - The acquisition of information from the customer, including complaints.
  - The acquisition of feedback from the customer, including complaints.

#### 5.4.3 Awareness

- The organization shall ensure that persons involved in CiP management are aware of:
  - Common management procedures for information management.
  - Reference to the guidelines and also the documented information defined by the organization to be necessary for the effectiveness of CiP management.

### Verification of Implementation

#### Reference

Check Sheet (Ver. 4.0)

**Questions**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Self-Evaluating Organization</th>
<th>Evaluation Result Verifying Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**Confidence judgment criteria, sample answers, points to note in management**

1. Do you manage the records related to CiP management?
   - Yes
   - No

2. Do you store operation records related to CiP management (the documents related to CiP management)?
   - Yes
   - No

3. Do you manage the records related to CiP management (the documents related to CiP management)?
   - Yes
   - No

4. Do you manage the records related to CiP management (the documents related to CiP management)?
   - Yes
   - No

5. Do you manage the records related to CiP management (the documents related to CiP management)?
   - Yes
   - No

6. Do you manage the records related to CiP management (the documents related to CiP management)?
   - Yes
   - No

### Conclusion

#### 5.7 Information and communication

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

- The acquisition of information on the laws, regulations and industry standards that the customer must comply with.
- The acquisition of feedback from the customer, including complaints.
- The acquisition of information from the customer, including complaints.
- The acquisition of information on the laws, regulations and industry standards that the customer must comply with.
- The acquisition of feedback from the customer, including complaints.
- The acquisition of information from the customer, including complaints.

#### 6.1 Customer communication

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

- The acquisition of information on the laws, regulations and industry standards that the customer must comply with.
- The acquisition of feedback from the customer, including complaints.
- The acquisition of information from the customer, including complaints.
- The acquisition of information on the laws, regulations and industry standards that the customer must comply with.
- The acquisition of feedback from the customer, including complaints.
- The acquisition of information from the customer, including complaints.

#### 6.2 Documents and information management

The organization shall manage and retain the information and information management systems as necessary for the effectiveness of the CiP management, in accordance with the following activities:

1. Document management
   - The organization shall establish and implement procedures related to the management of documents and information management systems, including:
     - Identification of documents and information management systems,
     - Classification of documents and information management systems (e.g., internal reference, reference, advanced),
     - Retention periods.

2. Information management
   - The organization shall establish and implement procedures related to the management of information and information management systems, including:
     - Identification of information and information management systems,
     - Classification of information and information management systems (e.g., internal reference, reference, advanced),
     - Retention periods.

#### Judgment reason, memo, remarks, etc.

- [Sample answers]
- [Points to note in management]
5.5.4.1 CiP information collection and verification

For the purpose of producing products which can meet the CiP management criteria in the stage of design and development, the organization shall determine the CiP management criteria for products and maintain them as documented information. The status of CiP information shall be maintained as documented information. The organization shall determine the CiP management criteria for products and maintain them as documented information. The criteria shall be kept in the departments concerned.

Verification of Implementation

Conformance judgment criteria, sample answer, points to note in management

<table>
<thead>
<tr>
<th>Process Control</th>
<th>Verification of Implementation</th>
<th>Conformance judgment criteria</th>
<th>Sample answer</th>
<th>Points to note in management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Control</td>
<td>Verification of Implementation</td>
<td>Conformance judgment criteria</td>
<td>Sample answer</td>
<td>Points to note in management</td>
</tr>
<tr>
<td>Process Control</td>
<td>Verification of Implementation</td>
<td>Conformance judgment criteria</td>
<td>Sample answer</td>
<td>Points to note in management</td>
</tr>
</tbody>
</table>

Sub-Classification

Question Flag

Basic
Advanced

Check sheet

[4/9]

Self-Evaluation

[4/9]

Result

[4/9]

Self-Evaluation Organization

[4/9]

By Evaluation Result Verifying Organization

[4/9]

Judgment section, remarks, etc.
<table>
<thead>
<tr>
<th>Questions</th>
<th>Conformance judgment criteria, sample answer, points to note in management</th>
<th>Self-Evaluation Result</th>
<th>By Self-Evaluating Organization</th>
<th>By Evaluation Result-Giving Organization</th>
</tr>
</thead>
</table>
| (1) Have you established and operated a CiP management system for your company? | Process Control: There is a document that requests that the supply establishment and operates a CiP management system for the purpose of controlling the quality of products, including chemicals, and to operate a CiP management system for the purpose of realizing the 

| (2) Have you conducted business with a supplier, do you need to verify that the CiP management status at the supplier? | Process Control: There is a system to verify the CiP management status at a supplier when selecting a supplier and it is implemented. The supplier management status including the management status with the first tier supplier to the company is confirmed. The confirmation is to be performed after the decision of the CiP management status at the first tier supplier. | Process Control: There is no system (verification details and verification method). | Process Control: The company verifies the management status published in a website or other open source. |
| (3) Have you established the management system? | Process Control: There is a system to verify the CiP management status at a supplier when selecting a supplier and it is implemented. The supplier management status including the management status with the first tier supplier to the company is confirmed. The confirmation is to be performed after the decision of the CiP management status at the first tier supplier. | Conformance: The judgment is made against the criteria defined in the "CiP management criteria" such as for the management system. | Conformance judgment criteria, sample answer, points to note in management |
| (4) Do you verify the method of re-verification? | Process Control: There is a system to verify the CiP management status at a supplier when selecting a supplier and it is implemented. The supplier management status including the management status with the first tier supplier to the company is confirmed. The confirmation is to be performed after the decision of the CiP management status at the first tier supplier. | Judgment record: There is no record of established and operated a CiP management system for your company. | Judgment record: There is no record of re-verification. |
| (5) Do you verify the non-conformance? | Process Control: There is a system to verify the CiP management status at a supplier when selecting a supplier and it is implemented. The supplier management status including the management status with the first tier supplier to the company is confirmed. The confirmation is to be performed after the decision of the CiP management status at the first tier supplier. | Judgment record: There is no record of re-verification. | Judgment record: There is no record of re-verification. |
| (6) Do you verify the verification results? | Process Control: There is a system to verify the CiP management status at a supplier when selecting a supplier and it is implemented. The supplier management status including the management status with the first tier supplier to the company is confirmed. The confirmation is to be performed after the decision of the CiP management status at the first tier supplier. | Judgment record: There is no record of re-verification. | Judgment record: There is no record of re-verification. |
| (7) Enter the details verified to identify if there is any process or any information for your own business or the supplier's products? | Process Control: There is a system to verify the CiP management status at a supplier when selecting a supplier and it is implemented. The supplier management status including the management status with the first tier supplier to the company is confirmed. The confirmation is to be performed after the decision of the CiP management status at the first tier supplier. | Judgment record: There is no record of re-verification. | Judgment record: There is no record of re-verification. |
| (8) In the results of the verification, do you verify the conformance? | Process Control: There is a system to verify the CiP management status at a supplier when selecting a supplier and it is implemented. The supplier management status including the management status with the first tier supplier to the company is confirmed. The confirmation is to be performed after the decision of the CiP management status at the first tier supplier. | Judgment record: There is no record of re-verification. | Judgment record: There is no record of re-verification. |
| (9) Enter the evidence-based method of verification and management when you respond to non-conformance? | Process Control: There is a system to verify the CiP management status at a supplier when selecting a supplier and it is implemented. The supplier management status including the management status with the first tier supplier to the company is confirmed. The confirmation is to be performed after the decision of the CiP management status at the first tier supplier. | Judgment record: There is no record of re-verification. | Judgment record: There is no record of re-verification. |

**I. Response to occurrence of nonconformance**

- If there are no requests from the supplier, the company will respond to the verification results as follows:
  - When non-conformance occurs:
    - For the purposes of satisfying the CiP management criteria, the company takes action against the supplier such as to demand improvement, instruct on improvement or stop the trade.
  - For the purposes of satisfying the CiP management criteria, the company verifies the management status published in a website or other open source.
  - Details including the above points are confirmed using various internal or third-party documents.
  - A record of the above points is recorded and confirmed through management status.

- The company verifies the management status published in a website or other open source.

**II. Management of the verification results**

- The company verifies the management status published in a website or other open source.

- Details including the above points are confirmed using various internal or third-party documents.

- A record of the above points is recorded and confirmed through management status.

**Conformance judgment criteria, sample answer, points to note in management**

- Nonconformance: There are no management criteria defined for conversion processes and parallel production, or else, there is no record of that system.

- Partial conformance: There are deficiencies in either the management criteria or the verification.

- Conformance: The details of the action to be taken for the target phenomena are defined.
5.5.4.3 CiP management at receiving

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.

The organization shall first define the action to be taken for the results of checks on the products purchased at the time of receiving. When the purchased products fulfill the CiP in purchasing are satisfied on the results of checks on the purchased products, the organization shall retain the result as documented information.

### Process Control

#### Main Classification

- **Verification of Criteria Existence**
- **Verification of Implementation**
- **Verification of Documentation**

#### Questions

**Item No. xx: Information delivery, Item No. xx : Requirement, Item No. xx: Evaluation**

- **Question Flag**
  - ++ ++
  - ++ ++
  - ++ ++
  - ++ ++

#### Result

<table>
<thead>
<tr>
<th>Check sheet</th>
<th>Conformance judgment criteria, sample answer, points to note in management</th>
<th>Self-Evaluating Organization</th>
<th>By Evaluation Result Testing Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-evaluating result</td>
<td>Conformance</td>
<td>Nonconformance</td>
<td>Conformance</td>
</tr>
<tr>
<td>Item No. xx</td>
<td>Information delivery, Item No. xx : Requirement, Item No. xx: Evaluation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

#### 5.5.5.3 Identification and traceability

The organization shall implement preventative measures against incorrect use and contamination for the chemical substances subject to the CiP management criteria.

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

#### Process Control

- **Verification of Implementation and Recording**
  - **Conformance judgment criteria**: The management method is defined and put in practice.
  - **Nonconformance**: There is no management method defined or the management method is not put in practice.

- **Verification of Recording**
  - **Conformance judgment criteria**: The management method is defined and put into practice.
  - **Nonconformance**: There is no management method defined or the management method is not put into practice.

#### Main Classification

- **Process Control**
  - **Verification of Implementation and Recording**
    - **Conformance judgment criteria**: The management method is defined, put into practice, and recorded.
    - **Nonconformance**: There is no management method defined, put into practice, or recorded.
  - **Verification of Recording**
    - **Conformance judgment criteria**: The management method is defined, put into practice, and recorded.
    - **Nonconformance**: There is no management method defined, put into practice, or recorded.

---

### Example Check Sheet

**Questions**

1. **Do you record the results of the judgment and decision of (3)?**
   - **Proposers**
     - **Conformance judgment criteria**: There is no judgment or decision of (3).
     - **Nonconformance**: There is a judgment or decision of (3).
   - **Proposed method**: Implement a judgment record method.

2. **Are there any processes or materials for which there is a risk of incorrect use or contamination with 'prohibited substances' as defined by the CiP management criteria, or any processes or materials for which this has not yet been verified?**
   - **Proposers**
     - **Conformance judgment criteria**: There are no processes or materials for which there is a risk of incorrect use or contamination with 'prohibited substances' as defined by the CiP management criteria.
     - **Nonconformance**: There are processes or materials for which there is a risk of incorrect use or contamination with 'prohibited substances' as defined by the CiP management criteria.
   - **Proposed method**: Conduct a check for processes or materials for which there is a risk of incorrect use or contamination with 'prohibited substances' as defined by the CiP management criteria.

---

### Example Check Sheet (Ver. 4.01)

**Questions**

1. **Do you have any document which defines the procedures to implement the management in (1) to (2)?**
   - **Proposers**
     - **Conformance judgment criteria**: There is no document which defines the procedures to implement the management in (1) to (2).
     - **Nonconformance**: There is a document which defines the procedures to implement the management in (1) to (2).
   - **Proposed method**: Create a document which defines the procedures to implement the management in (1) to (2).

---

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

**Questions**

1. **Do you have any document which defines the procedures to implement the management in (1) to (2)?**
   - **Proposers**
     - **Conformance judgment criteria**: There is no document which defines the procedures to implement the management in (1) to (2).
     - **Nonconformance**: There is a document which defines the procedures to implement the management in (1) to (2).
   - **Proposed method**: Create a document which defines the procedures to implement the management in (1) to (2).

---

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

**Questions**

1. **Do you have any document which defines the procedures to implement the management in (1) to (2)?**
   - **Proposers**
     - **Conformance judgment criteria**: There is no document which defines the procedures to implement the management in (1) to (2).
     - **Nonconformance**: There is a document which defines the procedures to implement the management in (1) to (2).
   - **Proposed method**: Create a document which defines the procedures to implement the management in (1) to (2).
The organization shall extract change elements which may affect the chemical substances subject to the CiP management and shall first conduct appropriate checks for any change in the CiP and conduct a review using the CiP management criteria.

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.

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.

### Verification of Implementation

<table>
<thead>
<tr>
<th>Sub-Classification</th>
<th>Common management</th>
<th>Verification of Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Points to note in management

- If there are separate rules for activities after shipping, then follow those rules.
- Changes subject to change management must include not only changes in the organization internally, but also any change made at the supplier or outsourcing organization.
- A manageability check is conducted when a change occurs.
- Changes subject to change management must include not only changes in the organization internally, but also any change made at the supplier or outsourcing organization.
- It is important that a change should be made after communicating with the customer.
- Changes subject to change management must include not only changes in the organization internally, but also any change made at the supplier or outsourcing organization.
- Information related to the change is a record of the communication of changes.
- The functions of the management department are defined in a document.
- The acquisition department conducts the CiP information management criteria before a change is made when a change occurs.
- The information is acquired, but the method or the department (person) is not defined.
- It is important that a change should be made after communicating with the customer.
- A manageability check is conducted when a change occurs.
- Changes subject to change management must include not only changes in the organization internally, but also any change made at the supplier or outsourcing organization.
- Changes subject to change management must include not only changes in the organization internally, but also any change made at the supplier or outsourcing organization.
- Changes subject to change management must include not only changes in the organization internally, but also any change made at the supplier or outsourcing organization.
- Information related to the change is a record of the communication of changes.
### Action Items (From Guidelines for the Management of Chemicals in Products (CiP) Ver. 4.0)

5.6 Performance evaluation and improvement

<table>
<thead>
<tr>
<th>Action Items (Details)</th>
<th>Verifications</th>
<th>Common management</th>
<th>Main Classification</th>
<th>Sub-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization shall evaluate the following items at predetermined intervals. The organization shall implement ... as documented information and shall report the results to top management. The top management shall review those results.</td>
<td>Verification of Documentation</td>
<td>Verification of Implementation</td>
<td>Basic</td>
<td>++</td>
</tr>
<tr>
<td>f) Improvement planning</td>
<td></td>
<td></td>
<td>Advanced</td>
<td>++</td>
</tr>
<tr>
<td>e) Effectiveness of actions to address risks and opportunities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Suitability of resources</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6) Supplier and external outsourcing contractor performance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5) Performance evaluation results</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Nonconformity and corrective action</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Conformance of products to CiP management criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Level of target achievement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Relevant communication with external stakeholders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Verification of Documentation</th>
<th>Common management</th>
<th>Main Classification</th>
<th>Sub-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Relevant communication with external stakeholders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Effectiveness of actions to address risks and opportunities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Information on CiP management performance and effectiveness, including regarding the following trends:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Situation of improvements and corrective action.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Level of target achievement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Performance evaluation results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Suitability of resources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Effectiveness of actions to address risks and opportunities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Improvement planning</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Verification of Implementation

<table>
<thead>
<tr>
<th>Question Flag</th>
<th>Item no. xx: Management review</th>
<th>Conformance judgment criteria</th>
<th>Sample answer</th>
<th>Points to note in management</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Do you evaluate the CiP management results periodically at a predetermined frequency?</td>
<td>Management review in (1) is that correction is necessary, do you implement corrective action?</td>
<td>Conformance judgment criteria</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the methods and records. Conformance: All the documents containing the systems and procedures to implement (1) to (3) above have been prepared.</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the methods and records. Conformance: All the documents containing the systems and procedures to implement (1) to (3) above have been prepared.</td>
</tr>
<tr>
<td>(2) When the result of the evaluation in (1) is the conclusion, do you implement corrective action?</td>
<td>Corrective action is necessary, do you implement corrective action?</td>
<td>Conformance judgment criteria</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the procedures and records. Conformance: The procedures for top management for CiP management related evaluation results and corrective action are defined and records are kept.</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the procedures and records. Conformance: The procedures for top management for CiP management related evaluation results and corrective action are defined and records are kept.</td>
</tr>
<tr>
<td>(3) Enter the name of the record which shows the results of reviews by the top management of the CiP management.</td>
<td>Management review report</td>
<td>Conformance judgment criteria</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the procedures and records. Conformance: The frequency of verification and the method and means for verification are decided and there are records of verifications performed following to those rules.</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the procedures and records. Conformance: The frequency of verification and the method and means for verification are decided and there are records of verifications performed following to those rules.</td>
</tr>
<tr>
<td>(4) Enter the names of the documents and the items specifying the criteria and the verification method.</td>
<td>Implementation details, evidence name, etc.</td>
<td>Conformance judgment criteria</td>
<td>Nonconformance: Only half or less of the documents have been prepared. Partial conformance: There are some parts that are insufficient. Conformance: All the documents containing the systems and procedures to implement (1) to (3) above have been prepared.</td>
<td>Nonconformance: Only half or less of the documents have been prepared. Partial conformance: There are some parts that are insufficient. Conformance: All the documents containing the systems and procedures to implement (1) to (3) above have been prepared.</td>
</tr>
<tr>
<td>(5) 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?</td>
<td>Conformance judgment criteria</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the procedures and records. Conformance: The procedures for top management for CiP management related evaluation results and corrective action are defined and records are kept.</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the procedures and records. Conformance: The procedures for top management for CiP management related evaluation results and corrective action are defined and records are kept.</td>
<td>Nonconformance: There are no records. Partial conformance: There are some deficiencies in the procedures and records. Conformance: The procedures for top management for CiP management related evaluation results and corrective action are defined and records are kept.</td>
</tr>
</tbody>
</table>

#### Conformance judgment criteria, sample answer, points to note in management

- **Nonconformance:** There are no records.
- **Partial conformance:** There are some deficiencies in the methods and records.
- **Conformance:** All the documents containing the systems and procedures to implement (1) to (3) above have been prepared.

#### Questions

- *What are the criteria for the verification of implementation?*
- *What are the methods and means for verification?*
- *Are there records of verifications performed?*
- *What are the details of the evaluation results?*
- *What are the criteria and verification methods for corrective action?*
- *Are there records for corrective action?*
- *What are the details of the management review report?*
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))

| **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: ................................................................. |
| **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 also be 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

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.
<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>27 Sept 2005</td>
<td>Guidelines for the Management of Chemicals in Product Ver. 1 Newly issued based on the Japan Green Procurement Survey Standardization Initiative (JGPSSI)</td>
</tr>
<tr>
<td>07 Nov 2006</td>
<td>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.)</td>
</tr>
<tr>
<td>02 July 2007</td>
<td>Guidelines for the Management of Chemicals in Products Ver. 1 Published by the Joint Article Management Promotion-consortium (JAMP) (members only)</td>
</tr>
<tr>
<td>31 Mar 2008</td>
<td>Guidelines for the Management of Chemicals in Products Ver. 2 (Version 2 published by both JGPSSI and JAMP as the outcome of joint efforts)</td>
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<td>20 Feb 2013</td>
<td>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</td>
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<td>1 Mar 2018</td>
<td>Guidelines for the Management of Chemicals in Products Ed. 4.0 Ed. 4.0 published as the joint study of “Collaboration Committee of Guidelines for the Management of Chemicals in Products Ed. 4” Compliance with JIS Z 7201:2017</td>
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- Japan Surface Finishing Suppliers Association (KZK)
- Japan Ship Machinery and Equipment Association (JSMEA)
- Japan Adhesive Tape Manufacturers’ Association (JATMA)
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These guidelines (Japanese version) are the publication by JAMP of the results of deliberations by the Collaboration Committee of Guidelines for the Management of Chemicals in Products Ed. 4. The English version is translated by JAMP and published as a reference document.

**Guidelines for the Management of Chemicals in Products (Edition 4.0)**

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