Guidelines for Quality Control of Registered Products

1. Purpose

The Guidelines are designed to show the fundamental concept for the quality control necessary to maintain the functions (antibacterial, antifungal, and antivirus activities) of the registered products, which are announced as one of the three SIAA product security standards, as well as explaining the self-management system specified as one of the membership requirements in the Admission Management Provisions.

Statements in the Guidelines regarding the definition and description of quality and quality control represent the SIAA's own approach for maintaining the quality of the registered products and may be different from the ones of each individual company (organization).

2. Scope of Application

The Guidelines apply to antibacterial agents, antibacterial processed products, antifungal agents, antifungal processed products, and antivirus processed products registered with the SIAA (hereinafter collectively referred to as the "Registered Products").

3. Meaning of the Establishment of a Self-Management System

Establishment of a self-management system is specified in the Admission Management Rules as one of the membership requirements. The following conditions are stipulated there:

・Agent manufacturers:

The company must have at least one test administrator or a person with equivalent qualifications.

・Processed product manufacturers:

The company must have a system to perform antibacterial evaluations in the company. It is also required that the company is supported by a testing organization that is a supporting member of the SIAA, or by an agent manufacturer that is a full member of the SIAA and conducts crosschecking with a supporting member.

The above means that, in order to confirm that antibacterial, antifungal, or antivirus activities (hereinafter referred to as the "Registered Functions") of the Registered Products satisfy the SIAA standards, the establishment of a system that can evaluate the Registered Functions of the Registered Products (agents or processed products) is required. This means that it is necessary as one of the membership requirements to voluntarily check the Registered Functions of the Registered Products and that it is also necessary to continue to do so even after becoming a member.

4. Concept of Quality Control

4-1. What Quality Means

As stated in Provisions for Control Managers (K11), quality means in the SIAA that the Registered Products satisfy the Voluntary Specifications for Quality and Safety (K07).

Therefore, maintenance of quality means that the Registered Products continuously satisfy the standards of the safety of the agent and the standards of the Registered Functions.

4-2. Concept of Quality Control

As a general rule, quality control is an activity to ensure high quality through three approaches: process control, quality inspections (product inspections), and quality improvement.

Process control is to plan, implement, and control each product manufacturing process in an efficient way in order to ensure the target quality. To be concrete, it includes standardization of work procedures, maintenance of facilities, and education and training for the work.

Quality inspections are to check whether the manufactured product complies with the product standard (target). Generally, it includes visual inspections and function inspections. Appearance inspections are to check whether there is any defect in appearance, such as scratches or dirt on the product, while function inspections are to evaluate the items in the product standards, such as the antibacterial activity function of a product, and confirm that it fulfills the specifications (product standards). Quality inspections do not simply mean the inspection of product quality but provide a good indication for judging the process control capability and effectiveness and, therefore, is an important activity for the maintenance of quality.

Quality improvement is about making improvements to prevent the recurrence of nonconformities in each process and inspections or to prevent what you think is a potential problem from occurring.

4-3. Process Management and Quality Inspection

In ISO 9000 Quality Management Systems - Fundamentals and Vocabulary (JIS Q 9000), the process approach is covered as one of the principles of quality management. The process approach means to understand and manage activities as interrelated processes that function as a coherent system. The important points of this approach include clarification of processes, consideration of interaction between processes, operation and management of processes, and application of processes as a system. There are many approaches that are shared with process control in the previous section.

There is an opinion that if process control is rigid, in other words, if the prescription for production is determined and products are manufactured according to it, the quality can be maintained without product quality inspections. However, quality inspections are also important as milestones, and both process control and product quality inspections are necessary for quality control.

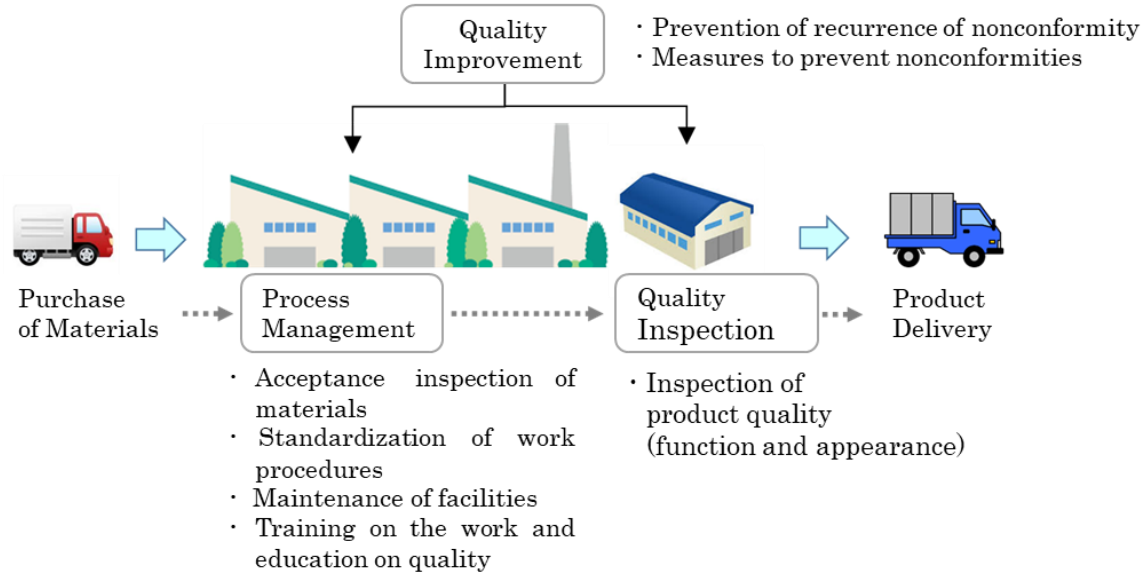
Generally, prescriptions for production (work standards) are determined for the purpose of keeping product quality within the scope of the standards by identifying the factors that exert an influence on product quality and controlling them to stay within a specific range. Looking from a different perspective, the prescriptions (standards) are designed to control

the factors identified at a specific time, and there are a few (or very few) cases where all factors that may influence product quality are covered.

Many organizations make efforts to maintain a certain level of quality by measuring specific parameters in the manufacturing conditions and parameters related to the items in the product standards for each lot, investigating the fluctuations, and implementing the necessary measures. Although these efforts represent one of the process control methods, they may also indicate that it is difficult to grasp and control all factors that exert influence on quality.

That is to say, although process control is indispensable for effective maintenance of quality, conducting process control alone is often insufficient. For important product functions, it is necessary to check on a periodic basis that the target level is achieved, even though there is an issue of frequency.

4-4. Schematic Chart of Quality Improvement



5. Checking the Registered Functions when the Ingredients of Registered Products are to be Changed

If the kind, volume added, and main base material (e.g., resin) of the agent used are the same and if the changed or added additives are determined to have no or very little influence on the Registered Functions (antibacterial, antifungal, and antivirus activities), the new product can be regarded to have the same specifications as the existing Registered Products. (Refer to the *M25 Product Registration Manual*.)

However, it is rare that the antibacterial effect of the additives changed or added is clearly identified, and the degree of influence may vary depending on the volume of the additives. Therefore, it is difficult in many cases to determine whether the specifications of the new product and the existing Registered Product can be regarded as the same.

For all these reasons, it is recommended to check the Registered Functions as a part of self-management when changing or adding ingredients of the Registered Products.

6. Self-management

The SIAA's principle is self-management of Registered Products. Self-management in this context means that member companies conduct process management and quality inspections (inspections of Registered Functions) as specified in Section 4 of this document on their own responsibility and check by themselves that the functions satisfy the SIAA standards in order to provide reassurance to consumers. The results need not to be regularly reported to the SIAA.

7. Periodic Performance Check System

Since its foundation, the SIAA's basic principle has been self-registration and self-management. Submission of the function data of Registered Products has been obligated

only at the time of product registration (at the time of entry to the SIAA and additional registration) and products that satisfy the specified standards have been allowed to bear the SIAA mark.

On the other hand, while awareness and globalization of the SIAA mark are growing, consumers' demand for safety and security is becoming more rigorous, and the social responsibility the SIAA mark assumes is increasing year by year. In recent years, a number of successive scandals, including falsification of quality data by leading manufacturers representing Japan, have become a social issue. As a result, general consumers' awareness of quality control and maintenance has been changing, and their interest in these issues has been increasing.

Under such circumstances, we decided to introduce a periodic performance check system in fiscal year 2021 in order to further increase the credibility of the SIAA mark. Under the system, member companies are requested to submit registered processed products to the secretariat once every five years, and their antibacterial activity is tested by a JNLA laboratory in accordance with JIS Z 2801. For details of the system, refer to the *Operating Manual on the Periodic Performance Check System*.

8. Summary

A product is manufactured through a series of processes and completed after checking its quality. In order to secure the target quality, it is essential to identify the factors that have an influence on product quality and control them to stay within a specific range. Quality inspections (inspections of Registered Functions) are also necessary to confirm the appropriateness of the process control.

Through appropriate process control and repeated quality inspection and improvement activities, we believe that the level of product quality can be maintained that is worthy of consumers' trust.

Formulated: March 16, 2021

(Attached)

Examples of Quality Control

Examples of quality control are shown below. Although you do not need to cling to these examples only, it is necessary to conduct both appropriate process control and inspections of the Registered Functions (antibacterial, antifungal, and antivirus activities). Quality improvement is also important in order to ensure stable product quality.

(a) Example of quality control of an agent manufacturer (manufacturing agents in-house)

- ✓ Process Control
  - ・ Establishing raw material standards and confirming that purchased materials satisfy them
  - ・ Manufacturing products in accordance with the specified manual and having the manufacturing records checked by an employee other than the worker engaged in the manufacturing process.
- ✓ Quality Inspection (Inspection of Registered Functions)
  - ・ Evaluating the antibacterial activity per lot, while its conformance with the product standards being checked by a quality assurance-related division
  - ・ Evaluating the antibacterial activity per lot or every three to six months (preferably every three months) at the company's facilities or at an external testing organization
- ✓ Quality Improvement
  - ・ Investigating the causes of nonconformities found in product inspections and carrying out corrective actions to prevent recurrences
  - ・ Investigating the factors that fall outside 3σ (standard value) among process parameters or in the parameter management during product quality inspections and taking preventive actions
  - ・ Investigating the causes of customer complaints and developing measures to prevent recurrences

(b) Example of a processed-product manufacturer A (adding antibacterial agents to the company's product)

- ✓ Process Control
  - ・ Establishing raw material standards and conducting acceptance inspections of antibacterial agents
  - ・ Manufacturing products in accordance with the specified procedures and checking the manufacturing records
- ✓ Quality Inspection (Inspection of Registered Functions)
  - ・ Evaluating the product's antibacterial activity in-house per lot or every three months
  - ・ Evaluating the product's antibacterial activity per lot or every six months at an

external testing organization

- Evaluating the product's antibacterial and antivirus activity every two years at a testing organization

✓ Quality Improvement

- Investigating the causes of exceeding or falling below the average consecutively for more than a specified number of times in the important parameter trend management during process management and taking preventive actions
- Investigating the causes of falling outside the standard values during product inspections and developing measures to prevent recurrences
- Reviewing the processes that you think have potential problems on a day-to-day basis and taking preventive actions
- Investigating the causes of customer complaints and developing measures to prevent recurrences

(c) Example of a processed-product manufacturer B (purchasing antibacterial parts and incorporate them into the company's product)

✓ Process Control

- Checking the product analysis table issued by the material manufacturer per lot purchased
- Manufacturing products in accordance with the specified procedures and checking the manufacturing records taken

✓ Quality Inspection (Inspection of Registered Functions)

- Obtaining antibacterial activity data of raw materials periodically (yearly) from their manufacturers and checking them and auditing suppliers as required
- Obtaining antivirus activity data of raw materials periodically (every two years) from their manufacturers and checking them
- Evaluating the Registered Functions of the company's end product periodically (at the company or at an external organization) (as required)

✓ Quality Improvement

- Checking with the material manufacturers for what makes the product characteristic value come close to the lower limit in the trend management at the time of acceptance inspection and asking them to implement the necessary measures
- Investigating the causes of scratches on the surface of antibacterial materials made during the manufacturing process and developing measures to prevent recurrences

(d) Example of a processed-product manufacturer C (purchasing antibacterial inks, paints, solutions, etc. and providing antibacterial printed materials and coating using them)

✓ Process Control

- Acceptance inspection of antibacterial inks, paints, and coating solutions (checking the ingredient analysis table)

- Printing in accordance with the conditions specified by the ink manufacturer (thickness of coating, mileage, etc.) and checking the result
- Painting in accordance with the conditions specified by the paint manufacturer and checking the result
- Coating in accordance with the conditions specified by the coating solution manufacturer (creating a manual of coating methods and checking the application)

✓ Quality Inspection (Inspection of Registered Functions)

- Antibacterial processed products: Evaluating antibacterial activity of the company's products every six months
- Antivirus processed products: Evaluating antivirus activity of the company's products every two years

✓ Quality Improvement

- Investigating the causes of nonconformities, including abnormal values, found in the inspections of printing machines or other equipment and developing measures to prevent recurrences
- Pursuing the causes of uneven application found in visual observation after the printing, coating, or painting process and developing measures to prevent recurrences
- Reviewing the conditions of printing and painting that you think have potential problems and taking preventive actions

(e) Example of processed product provider (purchasing products from other companies and selling them (including importers))

✓ Quality Control

- Concluding purchase specifications (a purchase and sales contract) that include the Registered Functions with the manufacturer
- Conducting acceptance inspections that include the Registered Functions
- Checking the data of the Registered Functions periodically (every six months for antibacterial and every two years for antivirus functions)

✓ Quality Improvement

- Discussing the causes of failure to meet the standard values in the regular checks of Registered Function data together with the manufacturer and sharing measures to prevent recurrences
- Investigating the causes of peeling or cracks on the coated or painted surfaces found in the periodic inspections and implementing countermeasures in cooperation with the execution companies