

This translation has been made based on the original collections of the interpretation by JISCBA

March 29, 2013

**[Common 15] Handling of on-site audit and the content of the product test when adding "Factory or business site" that has already received the certification of the same JIS to the JIS certification (Assumption of the factory to be added: Factory that is responsible for the process representing that of licensee to be added).**

Interpretation:

In case adding the "Factory or business site" obtaining the same JIS certification (hereinafter referred to as "factory"), perform on-site audit and conduct the items required for product test in accordance with the following cases. (The factory in this interpretation also includes other factory of the same legal entity as licensee)

**1. Content of on-site audit**

**<Case A> When the factory to be added has received JIS certification from the same accredited certification body (hereinafter referred to as "CB")**

- (1) When there is new possibility of risk of not conforming to JIS due to addition

Certification maintenance factory audit for the relevant factory and /or subcontract factory shall be conducted by on-site audit.

[Notes] Example for on-site audit

Due to the addition, when new quality or production condition (including a process, equipment, testing and inspection, replacement of identification and symbols associated with the addition, a mechanism for transferring information for approval of conformity and approval of shipment, etc.) or a combination thereof exceeds the scope of certification and/or the scope of quality control system at factory or at subcontractor's factory occur at the factory or subcontractor.

- (2) When a new quality or production condition (including a process, equipment, testing and inspection, replacement of identification and symbols associated with the addition, a mechanism for transferring information for approval of conformity and approval of shipment, etc.) or a combination thereof arises within the scope of certification and/or the scope of quality control system at the factory to be added.

- 1) When a new quality/production condition or a combination thereof is the main process (hereinafter referred to as the "main process" and the main process refers to the process determined to be critical to the quality by JISCBA and/or the respective accredited certification body.) etc.

On-site audit for the main process of the additional factory shall be conducted only when the CB determines that it is necessary to confirm by on-site audit to the additional factory, as determined by a) of JIS Q 1001 subclause 11.2 (modification or addition of the plant or business establishment), taking into account the quality of the production record since certification of the factory to be added (including the evaluation of the effectiveness of the educational training) and the stability of the operational critical control factors based on the conventional review.

- 2) When a new quality or production condition or its combination is other than the main process

On-site audit will not be made for other processes of the additional factory unless the CB determines that JIS Q 1001 subclause 11.2 (modification or addition of the plant or business establishment) results in the inherent need for on-site audit to the additional factory as a result of considering the quality of the production record since certification of the factory to be added (including the assessment of the effectiveness of educational training) and the stability of the operational critical control factors based on the conventional review.

**<Case B> When the factory to be added has received JIS certification from a CB that is different from the certification of the factory or business site to which it is added**

- (1) When there is a new risk of not conforming to JIS due to the addition

Same as (1) of <Case A> in 1.

- (2) When a new quality or production condition (including a process, equipment, testing and inspection, replacement of identification and symbols associated with the addition, a mechanism for transferring information for approval of conformity and approval of shipment, etc.) or a combination thereof arises within the scope of certification and/or the scope of quality control system at the factory to be added.

- 1) When a new quality or production condition or a combination thereof is a major process, etc.

Perform on-site audit of the main process concerned.

- 2) When a new quality or production condition or its combination is other than the main process

CB of the licensee of the factory to be added decide according to 2) of (2) of <Case A> in 1.

**2. Contents of the product test**

**<Case A> When the factory to be added has received JIS certification from the same CB as the certification of the factory to be added**

- (1) When there is a new risk of not conforming to JIS due to the addition

Perform certification maintenance product tests on the relevant factory.

[Notes] Example of performing product test

In conjunction with the addition, when a new quality/production condition (including process, equipment, test and inspection) that exceeds the scope of certification and/or the quality control system or the combination thereof occurs at the factory or/or subcontractor factory, and when the CB of licensee judges that it is required to be verified by product test under the specification of JIS Q 1001 subclause 11.2 (changes or additions to the factory or business site).

- (2) When a new quality/production condition (including process, Equipment, test/inspection, etc.) or a combination thereof arises within the scope of certification and/or within the scope of the quality control system received at an additional plant.

- 1) When a new quality or production condition or a combination thereof is a major process, etc.

A product test is conducted only when the CB determines that verification by product test is required under the specification of JIS Q1001 subclause 11.2 (changes or additions to the factory or business site), taking into account the quality of the production records since certification of the factory to be added (including the evaluation of the effectiveness of educational training) and the stability of operational critical control factors based on the conventional review.

- 2) When a new quality or production condition or its combination is other than the main process

Product test is not performed for any other process unless the CB determines that JIS Q 1001 subclause 11.2 (changes or additions to the factory or business site) will result in a specific need for product testing as a result of considering the quality (including the effectiveness assessment of educational training) and the stability of operational critical control factors based on the conventional review based on the production record since certification of the factory to be added.

**<Case B> When the factory to be added has received JIS certification from the different CB of the factory to be added to.**

- (1) Due to the addition, there is a new risk of not conforming to JIS.

Same as (1) of <Case A> in 2.

- (2) When new quality/production conditions (including processes, equipment, test/ inspections, etc.) or combinations thereof occurs within the scope of certification received at the factory to be added

- 1) When a new quality or production condition or a combination thereof is a major process, etc.

Conduct a product test of the product to which the critical process is applied.

- 2) When a new quality or production condition or its combination is other than the main process

CB of the licensee corresponds according to 2) of (2) of <Case A> in 2.

End of text