

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

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[Common 14] Handling of on-site audit and content of product tests when adding a factory or business site that has already received the same JIS certification as a "subcontracted factory".

Interpretation:

In case adding a factory or business site that has already received the same JIS certification, on-site audit and product test regarding required items shall be performed according to the following cases. (The subcontract factory in this interpretation also includes a different factory of the same corporation as the licensee.)

1. Content of on-site audit

<Case A> In case the subcontracted factory has received JIS certification from the same accredited certification body (hereinafter referred to as "CB") as the certification of the factory or business site to which it is added

- (1) In case there is a new risk of not conforming to JIS in connection with outsourcing consignment, certification maintenance review for the relevant factories is conducted by on-site audit.

[Notes] Example of on-site audit

In the event that a new quality or production condition (including a process, equipment, test and inspection, replacement of identification and symbols accompanying the entrustment/acceptance of consignment, and a mechanism of information transfer for approval of conformity and approval of shipment) exceeding the scope of certification and/or the quality control system received by the factory or a combination thereof occurs at licensee factory or an outsourcing factory incidental to the outsourcing.

- (2) In the event that a new quality or production condition (including a process, equipment, testing and inspection, replacement of identification and symbols associated with consignment/acceptance of consignment, and a mechanism for transferring information for approval of conformity and approval of shipment) or a combination thereof arises within the scope of certification and/or the scope of quality control system of certification to be received by the factory at licensee factory or an outsourcing factory.

- 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 of the main process is performed only when the CB determines that on-site audit is required by a) of JIS Q 1001 subclause 12.2 (temporal certification maintenance surveillance) as a consequence of considering the quality (including the effectiveness evaluation of educational training) based on the actual production results since the certification on the relevant factory and the stability of the operational critical control factors based on the conventional surveillance.

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

No on-site audit shall be made for the other process unless the CB has considered the number and content of the other process comprehensively and determines that there is an inherent need

for on-site audit as specified in a) of JIS Q 1001 subclause 12.2 (temporal the certification maintenance surveillance)

<Case B> When a subcontracted factory 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 incidental to the outsourcing consignment

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

- (2) In the event that a new quality or production condition (including a process, equipment, testing and inspection, replacement of identification and symbols associated with consignment/acceptance of consignment, and a mechanism for transferring information for approval of conformity and approval of shipment) or a combination thereof arises within the scope of certification and/or the scope of the quality control system to be received by the factory at licensee factory or an outsourcing factory.

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

On-site audit is required for 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 handles according to 2) of (2) of <Case A> in 1.

2. Contents of the product test

<Case A> When the subcontracted factory has received JIS certification from the same CB as the certification of the additional factory or business site

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

Perform certification maintenance product tests on the relevant factory.

[Notes] Example of performing product testing

When a new quality/production condition (including processes, Equipment, inspections, inspections, etc.) or a combination thereof that exceeds the scope of certification and/or the scope of quality control system of certification received by licensee arise incidental to the outsourcing, and the CB of licensee determines that confirmation by product test is required in accordance with the specification of a) in JIS Q 1001 subclause 12.2 (temporal the certification maintenance surveillance)

- (2) When a new quality/production condition (including process, equipment, test/inspection, etc.) or a combination thereof occurs in the scope of certification and/or the scope of quality control system of certification received by the relevant factory licensee factory or/or subcontracted factory "

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

On-site audit of the main process is performed only when the CB determines that on-site audit is required by a) of JIS Q 1001 subclause 12.2 (temporal certification maintenance surveillance) as a consequence of considering the quality (including the effectiveness evaluation of educational training) based on the actual production results since the certification on the relevant factory and the stability of the operational critical control factors based on the conventional surveillance.

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

No on-site audit shall be made for the other process unless the CB has considered the number and content of the other process comprehensively and determines that there is an inherent need for on-site audit as specified in a) of JIS Q 1001 subclause 12.2 (temporal the certification maintenance surveillance)

<Case B> When a subcontracted factory 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 incidental to the outsourcing consignment

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

- (2) When a new quality/production condition (including process, equipment, test/inspection, etc.) or a combination thereof occurs in the scope of the certification or/and the scope of quality control system of certification received by the relevant factory at licensee factory or/and subcontracted factory

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

Conduct product tests of products to which the main process concerned applies.

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

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

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