



## Session: Recertification



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January 23, 2018

# QUESTIONS & ANSWERS

A. General Questions			
#	Category	Question	Answer
A.1	Certification	How long before the CEIV certificate expires should entities begin the recertification process?	In order to ensure continuity, it is recommended the recertification process begin at least 6 months before the expiration of the CEIV certificate. Entities interested in recertification should reach out to the CEIV Pharma team for the latest version of the CEIV Pharma checklist in order to begin the process.
A.2	Validation	How many days of audit are needed for recertification?	Two (2) days onsite are needed given a full audit takes place during recertification.
A.3	Validation	Is the checklist used during recertification the same one used during the original assessment?	No. The latest version of the CEIV Pharma checklist will be used.
A.4	Validation	What happens if major or minor non-conformances (NCs) are identified during recertification?	If minor and major revisions are needed, the entity will have to take the appropriate corrective actions to close the gaps and resubmit the materials and evidence with changes made within one (1) month before the certificate's expiration date.

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A.5	Validation	If entity fails recertification, how much time do they have to close the NCs?	If an entity fails the recertification audit, they have until the CEIV Pharma certificate's expiration date to comply.
A.6	Validation	If entity fails recertification, will their CEIV Pharma certificate be suspended?	The CEIV Pharma certificate will be suspended only if the entity in question does not close the identified NCs before the expiration of the original CEIV certificate.
A.7	Validation	Can entities who fail the recertification audit handle pharmaceuticals while closing the identified NCs?	If an entity fails the recertification audit, they have until the original certificate's expiration date to comply. Failure to close NCs will result in removal from database as well as revoking of certificate.
A.8	Validation	Will the recertification audit be done by the same independent validator (IV) who conducted the initial certification?	In most of the cases IATA will send another IV.. A different IV will conduct the recertification audit. However, the IV may be the same one who conducted the initial assessment. In some cases IATA will send the same IV.
A.9	Validation	What if there is a discrepancy between the original certification and the recertification audits?	The recertification audit utilizes an updated CEIV Pharma checklist which supersedes the checklist used during the original certification. Three years is a long time, as such industry best practices and regulations will have changed.

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A.10	Training	What is the Training Requirement for the certification?	<p>As a reminder, each entity, in each location, needs to have at least:</p> <ul style="list-style-type: none"> <li>• 2 qualified key personnel who hold IATA Training certificate on the “Audit, Quality and Risk Management for Temperature Controlled Cargo Course (5 days)”;</li> <li>• and</li> <li>• 2 qualified competent personal who hold IATA Training certificate on the “Temperature Controlled Cargo Operations Course (3 days)”.</li> </ul>
A.11	Training	Will the recertification include refresher training for key personnel?	<p>Yes, the recertification includes refresher training for key personnel. To obtain the recertification, each entity, in each location, needs to train at least 2 of the qualified key personnel on the “CEIV Pharma Refresher Course for Key Personnel (2 days)”. The key personnel must hold the IATA Training certificate on the “Audit, Quality and Risk Management for Temperature Controlled Cargo Course (5 days)” in order to attend the refresher course.</p>

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A. General Questions			
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A.12	Training	What happen if the key personnel left the company or moved to another job?	In this case the entity needs to qualify new key personnel and he/she need to be trained on the “IATA Audit, Quality and Risk Management for Temperature Controlled Cargo Course (5 days)”.
A.13	Training	Will the recertification include refresher training for competent personnel?	The recertification does not include IATA refresher training for the competent personnel. However, the company must have at least 2 competent personnel who hold IATA Training certificate on “Temperature Controlled Cargo Operations Course (3 days)”. In addition, it is the responsibility of the entity to have internal training program and record of training, to give refresher and continuing training for competent personnel, as well as for all personnel involved within processing of temperature sensitive and healthcare shipments.

# QUESTIONS & ANSWERS

A. General Questions			
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A.14	Training	What happens if the competent personnel left the company or moved to another job?	In this case the entity needs to qualify new competent personnel and he/she needs to be trained on the “IATA Temperature Controlled Cargo Operations course (3 days)”.
A.15	Training	What happens if the entity does not have internal training program and record of training for all personnel?	It is in the program standards and requirements for a certified entity to have an internal training program with initial, refresher and continuing training program for all personnel involved within processing of temperature sensitive and healthcare shipments. Nonconformity will be classified as “Major” and must be corrected before the certification expiry date.

# THANK YOU

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