Certification
of Good Distribution Practices
for means of transport of sensitive products under controlled / regulated temperature

CERTIFICATION SCHEME
PR-06

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1. INTRODUCTION

Since its establishment in 1946, Refrigeration Research and Development Center COCH in Krakow Sp. z.o.o. has been meeting the needs of its customers by researching, designing and applying modern technical and technological solutions in the field of refrigeration. A natural consequence was a constant increase of the quality level of the services offered by COCH and undertaking new tasks, including certification.

In order to achieve the goals set in the area of product certification, a product certification body was established - Refrigeration Research and Development Center - Department for Product Certification, accredited by PCA in 1996.

Product Certification Body:

- acting as a subject of conformity assessment system in accordance with requirements included in PN-EN ISO/IEC 17065,
- responding to requirements concerning protection of public interest and feeling responsible for the quality of certification of products in the field of refrigeration, heat pumps and air conditioning,
- taking care to ensure credibility and trust in the scope of its activity, contributing to a constant improvement of competence level and removal of barriers in international exchange, sets itself the following strategic goals:
  - maintaining the high level of COCH activity of the Department for Product Certification, which contributes to increasing the interest of Polish manufacturers in certification of their products,
  - continuous improvement of COCH competences of the Department for Product Certification and responding to the identified needs to expand the certification system into new areas.

The Product Certification Body will achieve the strategic objectives outlined above by:

- ensuring independence, impartiality and confidentiality at all stages of certification;
- ensuring transparency of the certification system through publicly available information on its operations
- ensuring that the policy and procedures according to which the Certification Body operates do not discriminate and are not applied in a discriminatory manner towards applicants, also in respect of financial requirements
- to allow all parties to participate in developing policies and rules concerning the scope and operation of the certification scheme;
- improve the quality system that guarantees a high level of services provided by COCH to all interested customers;
- implementation of uniform rules for recruitment, monitoring and evaluation of employees (staff);
- ensure protection of information on clients and personnel involved in the certification process, as well as protection of their property rights;
- taking actions to raise awareness of the importance of product quality in business operations conducted by entrepreneurs;
- continuous involvement of the management and all employees in improvement of ways of performing their activities and searching for new areas of activity.

Operational objectives and the methods of their implementation are established and evaluated during annual reviews of the management of the Refrigeration Research and Development Center, in the organizational structure of which the product certification unit operates.

The policy and procedures included in the Quality Book and supplementary documentation are known to the personnel of the unit and applied at all organizational levels. The management shall undertake all actions necessary to fully implement the policy presented above.

2. SCOPE OF THE SCHEME

The PR-06 certification program of the Good Distribution Practice used in the EU, hereinafter referred to as (EU GDP), defines the conditions for obtaining the (EU GDP) certificate for means of transport (vehicles) intended for transport and storage of sensitive products (temperature-sensitive products). The program assumes, based on the requirements of the legislation and the results of many years of practice, that only refrigerated means of transport as vehicles with reinforced insulation are able to meet these conditions. The term "refrigerated means of transport" covers non-mechanically and mechanically cooled means of transport for the transport and storage of temperature-sensitive products (e.g. perishable foodstuffs, medicines), ATP-certified, whose body with a built-in, insulated body compartment is directly and permanently mounted on the trailer/semi-trailer body.

Obtaining the certificate (EU GDP) for a specific type/model of means of transport (vehicle) intended for transport and storage of sensitive products is available to each manufacturer/supplier, who provides stable organizational and technical conditions for production/supply of listed means of transport with specified parameters confirmed by appropriate tests.

The certificate may be issued for the means of transport (vehicle), which has the current ATP certificate and meets the requirements of this document to the extent specified by the manufacturer/supplier in the application for certification (certification of the full range of requirements and certification of the mapped temperature distribution).

A separate certificate shall be issued for each unit of a given model or type of transportation vehicle identified by a serial number.

Developed scheme based on the requirements outlined in:

1. The Act of 6 September 2001. - Pharmaceutical Law (Journal of Laws of 2008. No. 45, item 271, (as amended)
2. Regulation of the Minister of Health of 13 March 2015 on the requirements of Good Distribution Practice (Journal of Laws of 2015, item 381)
3. Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)
4. World Health Organization. Qualification of refrigerated road vehicles. QAS/14.558 Supplement 11. Technical supplement to WHO Technical Report Series, No.961,2011. Annex 9; Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products, August 2014
5. Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be used for such Carriage of 1.9.1970 (as amended)
6. Cemafroid (Fr)) : Specifications Particular to the Label “CertiCold Pharma”. TemperatureControlled Transport Equipment for Health Products. Revision 1. March 2014
7. PN-EN 378-1 Refrigerating systems and heat pumps - Safety and environmental requirements - Part 1: Basic requirements, definitions, classification and selection criteria
8. PKN-DIN SPEC 91323:2019-08 - Temperature conditioned transport equipment used for the distribution of pharmaceutical products (for human beings or veterinary use) - Guidelines for qualification

3. TERMINOLOGY

Definitions:

impartiality - maintaining objectivity;

certification – attestation by a third party of products, processes, systems or persons;

certificate - a statement of conformity issued by a Certification Body;

revocation - withdrawal, cancellation of a statement of conformity;

good distribution practice - a quality system setting out responsibilities, processes and rules of risk management related to distribution of temperature-sensitive products, including medicinal products

certification body - a body assessing conformity as a third party, acting in certification schemes;

customer - organization or person responsible to the Certification Body for ensuring that certification requirements including product requirements are met;

evaluation - combination of selection function and determination of conformity assessment activities;

appeal - request by the supplier of the conformity assessment object to the conformity assessment body or accreditation body for reconsideration of the decision taken by the body relating to this object;

procedure - a set way of carrying out an activity or a process; sensitive product - temperature-sensitive product;

certification scheme - certification system relating to specified products to which the same specified requirements, specified rules and procedures apply;

technical specification (specified requirement) - a need or expectation, which is specified in a normative document;

means of transport for sensitive products - a vehicle for transporting temperature-sensitive products under controlled/regulated temperature with permanently mounted equipment or a trailer;

complaint - an expression of dissatisfaction, other than an appeal by any person or organization, to a conformity assessment body or accreditation body concerning the actions of that body, requiring a response;

ATP certificate - a document certifying that the means of transport/vehicle meets the requirements of The Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage (ATP)

certification requirement - a specified requirement, including product requirements, which is fulfilled by the customer as a condition for establishing or maintaining certification

product requirement - requirement that refers directly to product, specified in standards or other normative documents identified in certification scheme

product - the result of the process: services, intellectual product, material object, processed materials;

certification scope - identification of a product, process or service for which certification is granted, applicable certification scheme and a standard or other normative document including its production date, with which conformity of the product, process or service is assessed

suspension - temporary cancellation of a statement of conformity or the entire specified scope of attestation or part thereof.

4. PRINCIPLES OF CERTIFICATION

4.1 Product certification process includes the following elements - program type (N) according to EN ISO/IEC 17067:

1. application review
2. product certification agreement
3. assessment of tests
4. review
5. decision - decision regarding granting, ending, suspension, withdrawal, renewal of certification
6. attestation - issuance of certificate of conformity.

4.2 Each vehicle of given model or type marked with serial number receives separate certificate.

4.3 The reference document for certification processes is the document: "WTP - 01/2015 COCH. *Requirements for Good Distribution Practice for means of transport of sensitive products transported under controlled/regulated temperature*". The certificate can be issued for a means of transport that complies with the requirements in full or in a scope limited to temperature distribution mapping.

5. CERTIFICATION – PROCEDURE

A supplier/manufacturer requesting certification or recertification receives initial information from the Department for Product Certification about:

- regulations concerning certification,
- scope of activity of Certification Body,
- certification rules,
- validity of certification,
- certification criteria (item 6 of this Program),
- principles of suspension and withdrawal of certificate,
- procedure of appeals and complaints,
- fees for certification,
- required forms,
- subcontracted activities (if applicable).

5.1. Submission and registration of the application

The supplier submits to the Department for Product Certification an application for conducting/re-certification, hereinafter referred to as the application.

Data and information included in the application necessary to perform certification process in accordance with the certification scheme:

- data concerning the certified product (means of transport), including the manufacturer's plate containing the type, model and brand of the vehicle and the factory number of the refrigeration unit and the type and weight of the refrigerant, refrigerant
- norms and/or normative documents to which the customer applies for certification
- scope of certification
- general information on the customer including name and address of the customer's physical location
- general information on the client, relevant to the area of certification requested, such as: the client's operations, its human and technical resources, including laboratories and/or technical means to perform inspections, and their functions and affiliations within the larger corporation, if any

- information on all subcontracted processes used by the customer that will affect conformity with the requirements, if the customer has identified a legal entity other than itself that manufactures the product to be certified
- all other information needed according to the relevant certification requirements, such as information on how the initial assessment was performed, e.g. the location where the certified product is produced and the contact persons at these locations.

5.2. Application Review

The review of the application is to ensure that:

- information about the customer and the product is sufficient to perform the certification process
- all known differences in understanding between the Certification Body and the client, including agreement on standards or other normative documents, have been resolved
- the scope of the requested certification has been defined
- the means to perform all assessment activities are available
- Certification Body had competences and possibilities to perform certification activity.

Review of the application is performed by an employee of Products Certification Department.

In case of identification of products, with which the Body had no previous experience, the products may be treated as of the same type, if the knowledge concerning requirements, features and technology related to one product is sufficient to understand the requirements, features and technology of another product.

In such cases, the Certification Body:

- ensures that it has the competence and capability to undertake all required certification activities and maintains a record of the justification for the decision to undertake certification
- refuses to undertake specified certification, if it lacks any competence or capability required to undertake such certification activity
- relies on certifications previously granted to this customer or certifications granted to other customers, then the Certification Body refers to the existing certification and provides justification for not performing the activity, if requested by the customer

5.3. Agreement on certification of product

After registration of the application, Certification Department prepares and sends to the supplier the agreement for product certification.

Signature of the agreement by the supplier is the prerequisite for continuation of procedure.

5.4. Review

The assessment is performed in accordance with the accepted plan. The supplier is informed of the accepted assessment plan. The assessment plan includes:

- test evaluation,
- personnel for assessment,
- list of necessary documents concerning the product and reference documents,
- results of product assessment performed by another accredited body (if applicable),
- way of informing the customer about identified nonconformities and additional actions verifying the execution of corrective actions,
- method of documenting the assessment results,
- date of the assessment realization.

5.4.1 Evaluation of product testing

The obligation to test certified products results from the certification system established by COCH.

The tests should be performed:

- when applying for certification (before granting the certificate)
- for initial tests
- during recertification.

Testing should be performed by accredited testing laboratories or laboratories, whose competences have been recognised by a Certification Body, and should cover all the requirements included in the standard or other normative document accepted as a reference document in the certification process.

The manufacturer/supplier may use the services of accredited laboratories of their choice, including foreign laboratories.

5.5. Overview

Review of all information and assessment results shall be performed by a representative of the Certification Body selected from the staff list.

The review shall include in particular the results of the evaluation of:

(a) product documentation;

(b) product tests;

and records of the use of previously granted certifications by the Certification Body to other clients.

5.6. Certification Decision

The results and documentation of the review are the basis for the decision on certification. Decision on granting the certificate is made by the Head of Products Certification Department.

Each vehicle of a given model or type marked with a serial number receives a separate certificate.

The negative decision (refusal) is sent to the supplier in written form with the justification. The same procedure is in case of recertification.

5.7. Validity period of the certificate

The validity period of the certificate is 3 years. Validity period of the certificate starts at the moment of granting the certificate.

Products Certification Department keeps the register of issued certificates.

5.8. Attestation - Certificate

The template of the certificate is the property of COCH and has been designed to protect it from forgery and inappropriate use.

The certificate contains records that uniquely identify the product to which the certificate applies:

- Name and address of the certificate holder and certificate number
- Type, type, brand of the vehicle
- Type and number of body/compartment
- Type and number of the refrigerating unit
- Validity period of the certificate
- No. of test report

- Name of normative/normative document (reference)
- Mark/ logo of the Certification Body (COCH)
- The statement "*The certificate is valid only for copies of vehicles having identical characteristics to the model submitted for testing in which the isothermal body and refrigeration unit will be maintained in working condition*."

The certificate may be published by the certificate holder in catalogs, manuals, publications. The Certification Body may make public information on the certificates issued.

5.9. Unit mark (label) and its disclosure

The product Certification Body has a mark (label) that can be used by the certificate holder for marking the product for which it has been certified within the full requirements of the reference document WTP - 01/2015 COCH. This mark shall contain the information:

- type of certification
- COCH logo and contact address
- date of validity of the certificate

The unit mark (label) should be placed (2 copies) on both sides of the vehicle body on the front lower corner. The unit mark may also be made available to the holder of the certificate in the form of an electronic record (file) and used by him for marketing purposes, e.g. in catalogs, instructions, etc. Conditions for the use of the certificate and the unit's mark (label) are specified in a certification agreement.

5.10. Advertisement

The holder of the certificate may use the certificate and the Certification Body's mark for advertising and marketing purposes, but in a way that unambiguously identifies the product to which they apply.

5.11. Impartiality, confidentiality and openness

A product certification body shall maintain independence, impartiality and confidentiality in its activities by:

a) ensuring that the policies and procedures under which the Certification Body operates do not discriminate against, and are not applied in a discriminatory manner to, applicants, their access to the services offered by the Body, including financial requirements and excessive requirements not clearly related to the scope of certification;
b) to enable all substantially interested parties to participate, in a balanced manner, in the development of policies and rules concerning the operation of the Certification Body and the design and implementation of the certification scheme;
c) to ensure impartiality with respect to other areas of COCH operations, in particular the lack of design and manufacturing processes for the products or services that will be subject to certification;
d) to ensure that independent actions can be carried out to protect impartiality with respect to decisions made by top management;
e) ensuring that services are available to all applicants whose activities overlap with the scope of the Certification Body;
f) to ensure transparency and openness in its operations through access to information necessary for the operation of the Certification Body and the implementation of the certification scheme;
g) g) assurance of protection of information on clients and staff involved in certification process and protection of their property rights

In particular, impartiality management will be implemented through:

- commitment of top management to impartiality; documenting actions to protect impartiality and confidentiality;
- ensuring equivalent representation of all materially interested parties; analyzing and identifying threats to impartiality and independence arising from its activities, the entity's or its personnel's relationships, and the activities of other persons, entities, or organizations (threat analyses) and taking appropriate action;
- ensuring objectivity, impartiality and absence of conflict of interest in activities during performance of tasks related to certification, including not participating in production, design of certified products or consulting on management system or auditing the customer's management system in the last two years;
- notification of management in case of conflict of interest; involvement in maintaining impartiality and confidentiality of all structures forming the Certification Body (management, Governing Board, Technical Committee, staff);
- ensuring access to all information necessary to protect impartiality; being able to undertake independent action if top management fails to respond to observations of a breach of impartiality.

Specifically, ensuring confidentiality will be accomplished by:

- the maintenance by staff of the confidentiality of information obtained in the course of their certification tasks within and after their employment;
- introduction of appropriate declarations and supervision over staff's activities; realization of requirements included in agreement for product certification and supervision; maintaining confidentiality of client's information obtained during processing of complaints and appeals.

In particular, ensuring the availability of information will be implemented through:

- publication of information on certification scheme, assessment procedures, rules and procedures for granting, maintaining and extending or restricting the scope of certification, suspending, withdrawing or refusing certification (handbook, website, information at Department for Products Certification);
- publication of information made public by the client or agreed with the client to be published, as well as information that the Certification Body is obliged to publish by law;
- general information on fees charged to applicants and customers; description of rights and obligations of applicants and customers, including the use of the Certification Body's name, certification mark and reference to certificates granted (agreement);
- information on procedures for handling complaints and appeals (handbook, website).

5.12. Use of certificate and unit mark

The unit supervises the ownership, use and display of unit certificates and marks by analyzing information on the users of transport services performed by certificate holders, press releases, Internet, etc.

Improper use of the unit's certificate or mark leads to suspension or revocation of the certificate, legal action, corrective action or publication of information on the infringement.

5.13. Termination and recertification

Appropriate actions by the Certification Body may include:

a) termination of the certification process;

b) recertification.

Termination of certification takes place on customer's request or as a result of Certification Body's decision as a result of customer's lack of information about continuing certification process within 6 months. Decision on termination of certification is made by the Head of Certification Department.

Re-certification

Validity of the certificate may be extended by recertification on supplier's request, submitted 30 days before expiry of the certificate. The procedure of recertification corresponds to the procedure of granting the certificate but it is not required to perform new tests of temperature distribution inside the body chamber (mapping).

After 12 years from the issuance of the first certificate, at recertification are required to re-test the temperature distribution inside the body chamber (mapping).

5.14. Liability

Responsibility for the product for which the certificate was issued is borne by the manufacturer / certificate holder

Product Certification Body requires from a holder of certificate:

a) keep records relating to any complaints about the conformity of the product to the requirements of the normative document and make these records available to the Certification Body on request;
b) take appropriate action in relation to those complaints and any defects identified in the products or services that affect their conformity with the requirements for certification;
c) to document the actions taken.

5.15. Appeals and complaints

The applicant for certification and the holder of the certificate have the right to appeal to the Chairman of the COCH Management Board against the decision of the Product Certifying Body which is unfavourable for them and which concerns, in particular:

- interruption of the certification process,
- refusal to grant the certificate,
- limiting the scope of certification,
- suspension, withdrawal / termination of certification.

The appeal, containing clearly formulated demands with their justification, is submitted to the Chairman of the Board in writing at the secretary's office of COCH within 14 days from receiving the disputed decision. The appellant receives a confirmation of receipt of the appeal. After the Chairman of the Board has considered the appeal, the unit shall immediately provide formal notification to the appellant of the outcome and completion of the process.

Documentation of appeals considered by the Chairman of the COCH Management Board is forwarded to the Product Certification Department within 14 days from the date of the appeal.

Complaints are submitted to the Head of Certification Department. After the complaint is reviewed by the Head, the unit immediately gives formal notification to the complainant of the outcome and completion of the complaint handling process.

Products Certification Department takes appropriate actions related to settlement of the appeal / complaint, including, if applicable, improvement of management system and certification activity.

The Body keeps records of all appeals/complaints received and actions taken by it in this respect.

5.16. Fees

The pricelist of maximum fees for certification is approved by the COCH Director and is available at the Department for Product Certification for everyone interested. Information on discounts is posted on the COCH website.

6. SCOPE OF CERTIFICATION

The scope of the Good Distribution Practice (EU GDP) certification includes the certification of vehicles for the transportation of sensitive products transported under controlled/regulated temperature: with permanently mounted equipment with semi-trailer for compliance with the requirements of the normative document "**WTP - 01/2015 COCH.** ***Requirements for Good Distribution Practice for means of transport of sensitive products transported at controlled/regulated temperature***" - Issue 3 dated 30.06.2020.

The basic requirements contained in the said normative document **WTP - 01/2015 COCH** include:

1. manufacturing and equipment
2. Functionality
3. Operation
4. Testing
5. Documentation
6. Labelling

7. RELATED DOCUMENTS

- Act of 6 September 2001. - Pharmaceutical Law (Journal of Laws of 2008. No. 45, item 271, (with later amendments)
- Regulation of the Minister of Health of March 13, 2015 on the requirements of Good Distribution Practice(Journal of Laws of 2015, item 381)
- Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)
- World Health Organization. Qualification of refrigerated road vehicles. QAS/14.558 Supplement 11. Technical supplement to WHO Technical Report Series, No.961,2011. Annex 9; Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products, August 2014
- The Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage dated 01.09.1970 (as amended)
- Cemafroid (Fr)) : Specifications Particular to the Label "CertiCold Pharma". Temperature-Controlled Transport Equipment for Health Products. Revision 1. March 2014
- PN-EN ISO/IEC 17065:2013-03: Conformity assessment — Requirements for bodies certifying products, processes and services.
- PN-EN ISO/IEC 17067:2014-01 Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes.
- PN-EN ISO/IEC 17000:2006 Conformity assessment — Vocabulary and general principles.
- PKN-DIN SPEC 91323:2019-08 - Temperature conditioned transport equipment used for the distribution of pharmaceutical products (for human beings or veterinary use) - Guidelines for qualification