Assessment of Compliance of Products Serving the Purposes of the National Security

E. Solinska, J. Wawrzyniak

The Institute of Security Technology "Moratex"

Introduction

In order to protect the interest of the Polish state in respect of defence and security, in the years 2006-2007 a number of legal regulations determining the principles of assessment of compliance of products ordered by the organisational units subject to or supervised by the Minister of National Defence and the competent minister of interior were implemented.

- The compliance assessment system in respect of products serving the purpose of the national security is governed by the following regulations:
- Act on compliance assessment system in respect of products serving the purpose of the national defence and security of November 17th, 2006 (Journal of Laws No. 235, item 1700),
- Ordinance of the Minister of Interior and Administration on organisational units empowered to assess the compliance of products serving the purposes of the national security of August 17th, 2007 (Journal of Laws No. 172, item 1216),
- Ordinance of the Minister of Interior and Administration on the method of determination of fees for activities involving examinations and certification of products serving the purposes of the national security of August 17th, 2007 (Journal of Laws No. 155, item 1094),
- Ordinance of the Minister of Interior and Administration on the method of supervision of inspection bodies and certification bodies of August 27th, 2007 (Journal of Laws No. 168, item 1183),
- Ordinance of the Minister of Interior and Administration on detailed method of supervision of the activities involving the product to be used in organisational and business units subject to or supervised by the competent minister of interior of August 29th, 2007 (Journal of Laws No. 170, item 1201),
- Ordinance of the Minister of Interior and Administration on detailed method of assessment of compliance of products serving the purposes of the national security and their list of September 25th, 2007 (Journal of Laws No. 188, item 1351),
- Ordinance of the Minister of Interior and Administration amending the ordinance on detailed method of assessment of compliance of products serving the purposes of the national security and their list of September 10th,2008 (Journal of Laws No. 169, item 1047).

The act on the compliance assessment system and the related ordinances determine:

- the principles of the compliance assessment of products serving the purposes of the national defence and security along with technical specifications,
- principles of detailed compliance assessment of products prior to introduction in organizational and business units subject to or supervised by the competent minister of interior,
- detailed lists of products subject of the compliance assessment to be used at organizational and business units subject to or supervised by the competent minister of interior,
- conditions to be fulfilled by the entities participating in the process of compliance assessment of products serving the purposes of the national defence and security,
- principles of supervision of functioning the compliance assessment system of products serving the purposes of the national defence and security.

The goals of introduction of legal regulations involving the compliance assessment of products serving the purposes of the national defence and security include:

- protection of the state interest in respect of defence and security by means of determination of principles of compliance assessment;
- providing conditions for competent and independent entities to carry out the product compliance assessment in respect of fulfilment of requirements contained in technical specifications;
- providing conditions to eliminate threats posed by the products to users' life and health and to the environment.

In accordance with the act, the system of compliance assessment of products serving the purposes of the national defence and security is created by:

- technical specifications
- regulations determining the method of compliance assessment
- regulations determining the operations of entities participating in the compliance assessment process.

At the same time, suppliers, inspection and certification bodies participate in the process of compliance assessment of products serving the purposes of the national defence and security.

The suppliers include enterprises supplying products to organizational and business units subject to or supervised by the Minster of National Defence and bodies, organizational and business units subject to or supervise by the competent minister of interior, including producers, distributors and importers.

Inspection bodies include organizational units with OIB accreditation assessing the compliance of a product on the basis of examinations and measurements to determine the compliance of the product with the technical specification.

Certification bodies include independent organizational units with OIB accreditation performing certification.

The assessment of compliance means activities of the supplier and the inspection body or the certification body to determine whether a product complies with the requirements specified in the technical specification. The assessment of compliance is carried out before a product is used. Irrespective of the assessment of compliance with the requirements determined in the technical specification, a voluntary assessment of compliance may be carried out according to the terms and conditions of the contract concluded by the parties concerned.

Depending on the features and technical parameters and threats the products may pose to users, the assessment of compliance of products to serve the purposes of the national security is carried out on three stages.

At stage one the supplier may carry out the assessment of compliance on its own. Stage two require participation of a research laboratory and stage three, which concerns products that may pose the greatest threat to the users, require participation of a certification body.

A positive result of the assessment of compliance of the product with the technical specification allows the supplier to issue an OIB declaration of compliance.

Activities of the Product Certification Department

The Product Certification Department, having the accreditation of the Polish Centre for Accreditation **AC 097**, has been operating at ITB „MORATEX" since 2000.

The certification included voluntary certification of commonly used products, including class I medical products, working clothes, protective clothes, protective equipment, etc.

The department has implemented and maintain the quality system compliant with the requirements of PN-EN 45011:2000 standard "General requirements regarding bodies implementing product certification systems" and PKN-ISO/IEC Guide 67:2007 "Assessment of compliance. Product certification basics.", which guarantees professional certification processes.

The certification of compliance is carried out on the basis of national and foreign standards, directives and other normative documents specified by the supplier.

ITB "MORATEX" is also a notified body No. 1475 in respect of the Directive.

Currently, the priori thy of the Department's activities is the assessment of compliance of products to serve the purposes of the national security used at organizational units subject to and/or supervised by the Minister of Interior and Administration, i.e. the Police Headquarters, Border Guards, and the Government Protection Bureau in accordance with the act of November 17th, 2006 on the system of assessment of compliance of products to serve the purposes of the national defence and security.

In 2008, the Product Certification Department was accredited by the Ministry of Interior and Administration, accreditation no. CA-OiB-004.01/2008.

The OiB certification includes the following product groups:

- skin protection devices (filtration and barrier protective clothes),
- ballistic protection equipment and measures (protective bulletproof vests, fragment-proof vests, knife-proof vests, needle-proof vests and others, protective helmets, protective covers, impact-proof covers),
- firework equipment,
- uniform equipment objects.

The Product Certification Department issues voluntary certificates for the materials used in the aforementioned products.

Certification programmes and systems

The certification activities are carried out on the basis of certification programme and systems.

The certification systems determine the principles and procedures and management used in the compliance assessment system.

The certification programs determine the principles of conduct referring to specific products to which the same specialized requirements, specific principles and procedures apply.

The Product Certification Department performs certification of compliance of products according to the certification systems 1b, 3, 5, 7 (in accordance with PKN-ISO/IEC Guide 67:2007).

Certification system 1b involves only the assessment of product type, including:

- taking samples,
- determination of features on the basis of sample examination,
- assessment of examination reports,
- decisions,
- issue of compliance certificates.

Certification system 3 involves certification of compliance of products manufactured in series, including:

- taking samples;
- determination of features on the basis of sample examination;
- initial assessment of the production process or the quality system, if applicable;
- assessment of examination reports;
- decisions;
- issue of compliance certificates;
- supervision in the certificate validity period, including periodical controls of the production process quality system of the supplier and examination of assessment of quality of samples taken from the supplier.

Certification system 5 involves certification of products manufactured or supplied in series and includes quality system examination and assessment. With respect to supervision, the certification body supervises the maintenance of the quality system and continuity of compliance of products by means of examination of samples taken from the market or the place of production or from both of them.

The system includes:

- taking samples;
- determination of features on the basis of sample examination;
- assessment of the supplier's quality system or technical and organisational conditions and its effectiveness;
- assessment of examination reports;
- decisions;
- issue of compliance certificates;
- supervision of the organization of the production process or the quality system or both of them;
- continuous supervision of the product by means of examination or inspection of samples from the factory or market or from both of them.

Certification system 7 involves certification of clearly specified batches of products and includes:

- taking samples;
- sample examination;
- assessment of compliance of a batch of product with the requirements;
- decisions;
- issue of a certificate of compliance with clearly determined requirements for duly identified product batch;
- supervision of correct use of the certificate.

Programmes

The Product Certification Department has prepared 5 certification programmes including the principles of procedure regarding products to which the same specialized requirements, determined principles and procedures apply.

PC OiB-01 Certification Programme includes certification of clothes, including:

- skin protection equipment and measures
- firework equipment
- uniform equipment objects.

PC OiB-02 Certification Programme includes certification of protective vests.
PC OiB-03 Certification Programme includes certification of protective helmets.
PC OiB-04 Certification Programme includes certification of protective covers.
PC OiB-05 Certification Programme includes certification of impact-proof covers

The certification system is chosen on the basis of the product type and supplier's nature. The certification systems have been determined in the basis of PKN-ISO/IEC Guide 67:2007 "Assessment of compliance. Product certification basics." Depending on the certification system applied, the certification process stages have been presented in the table below:

Table 1 Certification process stages

	Certification process stages	**Certification system**			
		1b	**3**	**5**	**7**
1.	Submission of an application including: — full Supplier's data — producer's data of the supplier is an importer or distributor — full product data — declaration on covering costs of the certification process	X	X	X	X
2.	Appendices to the application:				
	• documentation of the product containing identification of materials, description of production processes, tables of measurements, technological and utility parameters, application of the standard, marking method, maintenance principles, packing method, description of the quality control method	X	X	X	X
	• questionnaire of the Supplier	-	X	X	-
	• product model	X	X	X	X
	• results of laboratory research	X	X	X	-
3.	Application registration	X	X	X	X
4.	Formal assessment of the documentation submitted	X	X	X	X
5.	Initial fee for review of the application	X	X	X	X
6.	Conclusion of contract for certification process	X	X	X	X
7.	Taking samples by the body from the product batch	-	-	-	X
8.	Laboratory examination of the products taken from a batch	-	-	-	X
9.	Assessment of the quality system or technical and organisational conditions	-	-	X	-
10.	Assessment of documentation of the product certified	X	X	X	X
11.	Assessment of results of laboratory examination	X	X	X	X
12.	Decision of the Technical Committee	X	X	X	X
13.	Decision on whether the certificate is given or not	X	X	X	X
14.	Free for the certification process (irrespective of the result)	X	X	X	X
15.	Contract for issue and supervision of the certificate	X*)	X	X	X
16.	Issue of the certificate	X	X	X	X
17.	Supervision:				
	• examination of samples taken from the recipient	-	-	X	X
	• examination of samples from the plant	-	X	X	X
	• quality system audits connected with random examinations	-	-	X	-
	• production process assessment	-	X	X	-
*) The contract regards issue of the certificate only					

Certification process stage

Preparatory procedure

Prior to submission of the application for certification of a product, the supplier will agree the following with the PCD in an explicit and clear way:

- certification scope and system,
- requirements to be met by the product introduced to trading, i.e. standards and normative documents determining requirements and examination methods,
- principles of taking samples to examinations,
- type and scope of the documentation identifying the product,
- certification process costs and examination costs.

Submission of an application

After the stage of arrangements, the supplier submits the application for certification along with:

- technical documentation necessary to perform the compliance assessment,
- appropriate number of product items,
- manual describing safe use,
- information about maintenance,
- for products manufactured in series, information regarding the quality management system.

Formal assessment of the application

Prior to registration, the application is subject to formal assessment. In the case of a positive result, the application is registered. If the application requires supplementation, the Product Certification Department provides the supplier with a list of irregularities.

After supplementation of the application with lacking information, the application is registered.

Product examinations for the purposes of the certification

Product examinations the results of which are used in the certification process are carried out by any testing laboratory independent of the supplier and accredited within appropriate scope.

The PCD maintains and regularly updates a list of testing laboratories accredited by the PCA the scope of which includes examinations required to the product certification.

Taking products for examinations

Products for examinations for the purposes of certification should be taken by the supplier randomly, in accordance with the requirements of the standard in question. The products for examinations should be representative for the whole supply. In the case of certification of a batch of products, the PCD takes a blind sample from a clearly identified batch of products with numerousness depending on the number of items in the batch. The samples are taken from different places of the batch. Each time, a report is prepared on taking samples.

Examination report

The PCD admits examination reports prepared by national or foreign accredited testing laboratories.

Assessment of the quality assurance system or technical and organisational conditions of the supplier

If the supplier maintains a certified quality assurance system, the PCD may admit the system certified and resign from performing control at the supplier's place after making sure that the certificate is valid and has appropriate scope.

In the case the applicant did not submit a declaration on the quality assurance system applied. The PCD assesses technical and organisational conditions necessary to ensure repeatable and good supply.

Review and assessment of materials collected during the product certification process

After confirmation of paying the initial fee, the application along with the documents attached is analyzed by an employee of the PCD. The result of the analysis in the form of assessment of the documentation of the applicant for issue of the certificate for a product are presented and discussed at the meeting of the Certification Technical Committee.

The opinion of the Committee is conveyed to the Manager of the PCD.

Decision on whether the certificate is issued or not

The Product Certification Department issues a certificate of compliance if it finds that the product complies with the documentation necessary to perform the compliance assessment and in the case of a product manufactured in series, also that the quality management system of the supplier complies with the required standards. The certificate validity is three years as of the issue date.

In the case of refusal of issue of the certificate, the supplier receives a written justification of the refusal, settlement of costs of the certification process along with information about the method of appeal from the decision.

Interruption of the certification process

It is permitted to interrupt the certification process of a product if the supplier submits a letter to the PCD on interruption of the certification process, fails to comply with the terms and conditions of the contract for certification process, or fails to adhere to the financial liabilities towards the PCD.

Information confidentiality

The PCD ensures confidentiality of the information obtained in the certification process, except for special cases provided for by legal regulations. All employees of the PCD and employees of units providing services related to the certification process are obliged to maintain confidentiality.

Supervision of the certificate issued

The certificate may be used solely by the owner in accordance with the contract for the issue and supervision of the certificate.

The holder of the certificate issued by the PCD is obliged, in particular, to:

- apply the certificate solely to the products meeting the determined requirements and for which it was issued;
- not to lend it for use by another natural or legal person;
- inform the PCD about any and all intended changes regarding the product certified, its production process and quality assurance system.

The PCD supervises the certificates issued by it by means of:

- supervision of the way of use of the certificate by the supplier;
- control of results of examinations of uncompleted products covered by the certificate, taken from the supplier and / or purchased in the market, performer in the accredited or authorized laboratories;
- supervision of technical and organizational conditions at the supplier's place during the certificate validity;
- assessment of the supplier in respect of correct functioning of its quality system.

Suspension, invalidation or cancellation of the certificate

Incorrect reference to the certificate issued or its incorrect application results in suspension or cancellation of the certificate. The principles and conditions regarding suspension, invalidation and cancellation of the certificate have been contained in the contract for issue and supervision of the certificate.

The PCD may suspend the certificate if:

- it finds that the product fails to conform with the requirements of the normative document determined in the certificate;
- negative results of controls or examinations of products conducted within the confines of supervision of the certificate are obtained;
- the supplier (applicant) renders it impossible for the PCD to conduct inspection or control of the product;
- the supplier (applicant) fails to comply with the terms and conditions specified in the contract with the PCD;
- the supplier (applicant) applied for suspension of the certificate on account of temporary production stoppage.

When suspending the validity of the certificate, the PCD determines the conditions pursuant to which the certificate may be resorted and the date of their fulfilment. If the safety requirements are not met, the suspension takes place with immediate effect.

The certificate is invalidated of the holder resigns from the certificate and submits a written application for its invalidation.

The certificate is cancelled if:

- the supplier (applicant) intentionally abuses rights resulting from the certificate;
- the supplier (applicant) fails to meet the requirements of the PCD within the determined period when suspending the validity of the certificate and the change of the period is not agreed earlier;
- the supplier (applicant) suspended at its own request and failed to take activities aimed at restoration of the certificate.

Extension and limitation of the scope of the certificate

The extension regards a product that has already received a certificate and which the producer wants to introduce tiny changes to, e.g. in the product structure or use of additional resources. Introduction of changes may not influence the requirements for the product contained in the certificate issued.

The PCD provides a possibility to extend the scope of the certificate after simplified certification process (without assessment of the supplier's quality system). The scope of the process and the documentation required is determined by the PCD.

The extension is made in the form of an annexe to the certificate for the basic product with the same validity period.

The limitation of the scope of the certificate may take place at the request of the holder if it ceased the production of a determined product version included in a certified type of products.

Extension of validity of the certificate

The extension of validity of the certificate regards a certificate that becomes invalid and takes place at the request of the certificate holder on the basis of:

- positive results of examinations and controls carried out within the confines of the supervision of the certificate;
- positive results of additional examinations for the product required by the PCD at the moment of extension of the certificate validity;
- lack of objections as to observance of all provisions of the contract concluded between the PCD and the supplier;
- lack of users' complaints about the product;
- Lack of objections as to the correct use and application of the certificate held by the supplier;
- positive results of the simplified certification process;
- settlement of financial liabilities towards the PCD for extension of the certificate validity by the supplier.

In the case of extension of the certificate validity, the applicant submits an application for extension of the certificate validity one month prior to the expiry of the validity. The validity of the certificate may be extended by up to 5 years and regards the same product.

Transfer of ownership rights to the certificate

In the case of a change of the legal status of the certificate holder, it may apply for transfer of ownership rights to the certificate.

The applicant should attach the following documents to the application for transfer of ownership rights:

- confirmation of transfer of ownership rights,
- confirmation of change in the relevant register,
- declaration on assumption of the rights and obligations of the previous certificate holder.

The quality system or technical and organisational conditions of the applicant for transfer of ownership rights to the certificate will be assessed like in the case of the supplier.

Fees for certification and supervision of the certificate issued

Total costs related to the product certification process and costs related to supervision of the certificate issued are incurred by the applicant / holder of the certificate irrespective of the result of the certification process.

The costs of the certification process and supervision are determined individually and the value thereof is determined in the contract. The fees for the certification process are charged at two stages:

- on submission of the application for certification of a product by the supplier (initial fee),
- after completion of the certification process (full settlement of costs).

The costs of laboratory tests are not included in the costs of the certification process and comply with the price lists of the accredited laboratories making the tests.

Appeal from the decision of the PCD

If the supplier does not agree with the decision on refusal to issue, refusal to extend, suspension or cancellation of the certificate, it is entitled to appeal from the decision with the Institution Director within 30 days as of the notification.

If the appeal is not approved by the Director, the Customer may appeal to the Court having jurisdiction over the Institute of Security Technology "MORATEX".

The certificate of ITB „MORATEX" confirms the compliance of the product with the requirements, safety of the product for people and the environment and the reliability of producers. Furthermore, the certificate enhances the reliability and rang of the product, which is a priority in the case of elimination of threats posed by products serving the purposes of the country's defence and security.

The certificate allows the supplier to issue the OiB declaration of compliance and shortens the activities of the body supervising the activities related to introduction of a product for use.