



ANNUAL ACTIVITY REPORT

2016

Bulgarian Institute for Standardization

Standards – always a step ahead

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INTRODUCTION

Again, as every year, we bring to the attention of our members, clients and partners the Activity Report of the Bulgarian Institute for Standardization (BDS) for 2016.

Over the past year BDS continued to strengthen and build on the results achieved with the successful implementation of „Improving the standardization system in Bulgaria“ project, financed under OP „Competitiveness“. The upgraded BDS website allowed us to establish an online access platform for BDS/TC members and experts to BDS/TC documents and to vote on these documents. This platform was enlarged with new stages in 2016 in line with the best European practices.

BDS is working on establishing a platform for public enquiry of draft standards that will be accessible to all interested parties in Bulgaria. We do all this aiming to meet the transparency and accessibility requirements for the standardization activities set by Regulation 1025/2012 on the European standardization.

By opening new Information Centres on Standardization at universities - they are nine by now - we enable hundreds of students and lecturers to read standards and to gain knowledge on standardization. We also continue to publish collections of standards, thus enabling small and medium businesses in Bulgaria to buy the most necessary standards at affordable prices.

We had elaborated BDS marketing strategy for the period 2016 – 2025, adopted by BDS Governing Board in February 2016, and we have started its implementation.

In the past year we started to revise our quality management system in line with the new edition of BDS ISO 9001:2015, we identified the risks and opportunities related to the basic processes in BDS and defined measures for their management.

BDS continued to successfully perform in 2016 its mission and to realize its vision as an institution with European image and of national significance. Our efforts in this respect are highly appreciated by the governing bodies of the European standards organizations, and some of our practices are recognized as good practices at European level.

At the same time we continue our efforts to cope with the challenges of the changing market environment in Bulgaria and to ensure the stability of the institution BDS.

Iren Dabizheva
BDS Managing Director



10 YEARS BDS AS A PUBLIC-LAW ORGANIZATION

In April 2016 we marked ten years from the first (constituent) General Assembly of the Bulgarian Institute for Standardization (BDS) in Sofia. Over 450 representatives of companies and organizations participated in the establishment of BDS as a public - law membership organization operating for the public benefit of society on 10 April 2006 at the Central Military Club. The founder members adopted BDS Statute and elected the members of the Governing Board and of the Control Board. The amount of the membership fee was also fixed. On 10 April 2006 the standardization reform that had started with the adoption of the Law on National Standardization in 1999 was successfully completed. This law changed the status of standards - from mandatory to voluntary. The word „state“ was removed as ownership was no longer only state ownership. But the contradiction between the governmental status of the national standardization body - at that time the State Agency for Metrology and Standardization (SASM) and the technical committees that were set up on completely different principles - electivity and voluntary involvement of stakeholders remained.

The statute of BDS was also changed - from an administration of the executive power to a public legal organization, analogous to which is the association for public benefit of society within the meaning of the Law for the Non-Profit Corporate Bodies (legal entities). This is the predominant model amongst CEN and CENELEC members. Such organizations are usually called in Europe organizations that do not distribute profits.

The changes in BDS set-up, organization and structure refer both to the management bodies and to the technical working bodies (technical boards, technical committees and other technical working bodies) and are driven by the practice and efficiency of national standardization activities. The principles of democracy, voluntary, equality, balance and transparency are laid down in BDS Statute, in the Rules for National Standardization Activities and are directly applied to the election and decision-making by the governing bodies and the technical working bodies.

The present Strategy for Development of the Standardization System in Bulgaria and for Development of the Bulgarian Institute for Standardization (BDS) for the period 2014-2017 was elaborated in a clearly defined strategic planning process. The laid down BDS mission is to democratically recognize, bring closer, harmonize and balance the interests of all interested in standardization private, public and civil entities. BDS ensures effectively the respecting of the value-based principles for standards development at all levels (national, European and international) by attracting and engaging with standardization activities the producers, suppliers, consumers, governmental bodies and public organizations, social partners, conformity assessment bodies, scientific and academic circles and non-governmental organizations.

The followed by BDS vision in 2014-2017 is to be an institution with European image and of national significance that is recognized at national level as well as in the global world, endeavoring to bring together and reflect the interests of all stakeholders, that offers standards, services and solutions of the highest quality.

Ivelin Burov
Chairman of
BDS Governing Board



BDS MEMBER ORGANIZATIONS IN 2016

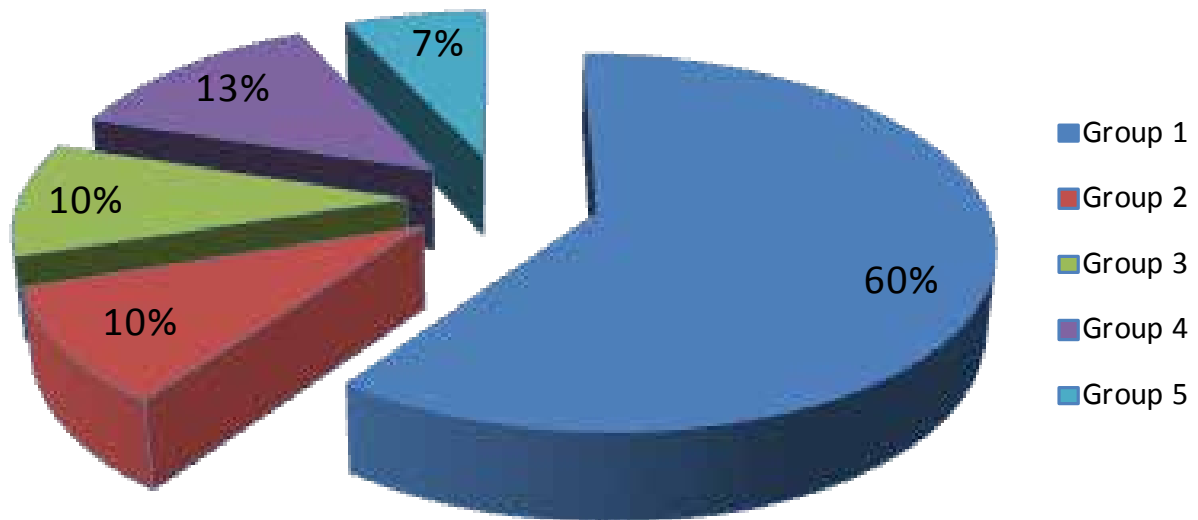
The picture of BDS member organizations at the end of 2016 was as follows: a total of 326 organizations (legal entities). 10 of them were corporate members, 293 had the status of active members, 18 had observer status and 5 organizations were of a mixed status – active one and as observers.



Annual activity report 2016

Their distribution by groups is presented in the following table, and the graph below illustrates their percentage ratio:

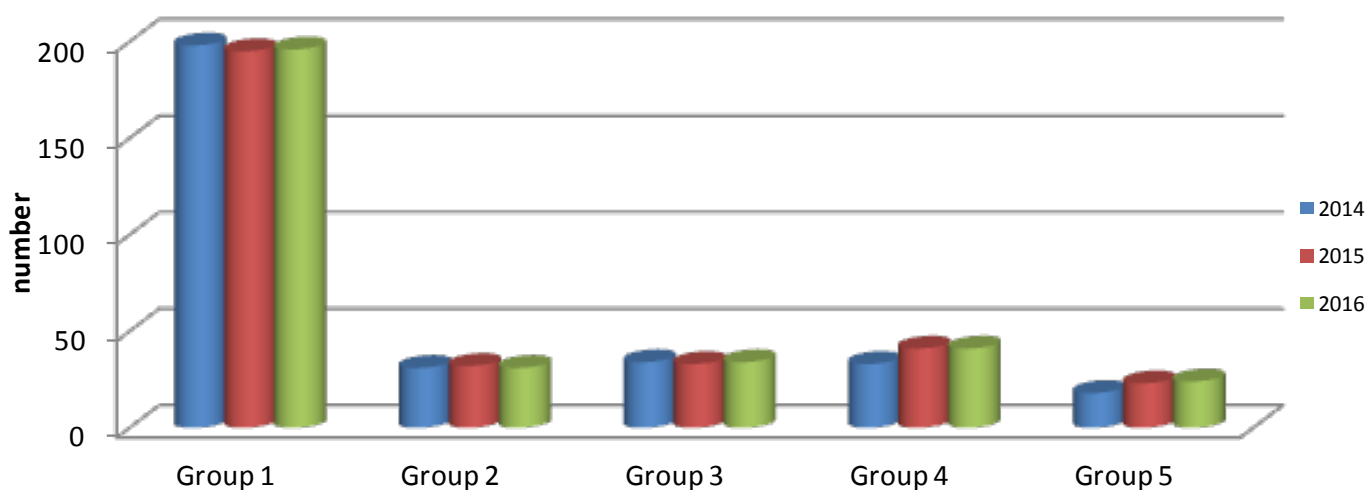
Group	Type of organization	Number
Group 1	Employers' associations, branch chambers, producers and traders, banks	196
Group 2	Executive government bodies	31
Group 3	Scientific organizations, institutes, universities	34
Group 4	Conformity assessment bodies	41
Group 5	Insurance associations, professional organizations, unions	24
Total		326



BDS member organizations in 2016

The change in BDS members for three consecutive years is presented in the table and graph below:

Group	Type of organization	2014		2015		2016	
		Number	%	Number	%	Number	%
Group 1	Employers' associations, branch chambers, producers and traders, banks	198	63	195	60	196	60
Group 2	Executive government bodies	31	9	32	10	31	10
Group 3	Scientific organizations, institutes, universities	34	11	33	10	34	10
Group 4	Conformity assessment bodies	33	11	41	13	41	13
Group 5	Insurance associations, professional organizations, unions	18	6	23	7	24	7
Total		314		324		326	



Comparison of the number of BDS members for 2014 – 2016 by groups

Annual activity report 2016

The distribution in the biggest group is as follows:

Group 1	Type of organization	Number	%
	Employers' associations, branch chambers	21	11
	Producers and traders:		
	Micro enterprises	32	16
	Small enterprises	49	25
	Medium enterprises	46	23,5
	Large enterprises	46	23,5
	Banks	2	1
	Total	196	

BDS members participate with their experts in the standardization work of BDS technical committees (BDS/TC). The total number of the experts (**individuals**) by 31.12.2016 was **1154**.

One of the main tasks also in 2016 was the involvement of new members. As a result of the efforts made, the number of newly involved organizations, interested in the standardization activity, was 20.

Annual meeting of experts of BDS/TC 28 "General metrology"



BDS ACTIVITIES AT NATIONAL LEVEL

The Bulgarian Institute for Standardization continued in the past 2016 to operate in accordance with its normative documents that define its authority, duties and responsibilities, and in line with the published national standardization work programme.

The work of the Technical Committees (BDS/TC) was in accordance with the approved standardization programme, which was accessible to all interested parties and announced on the website. The work programme covered items for development of Bulgarian standards at national level, items for implementation of international and European standards by translation into Bulgarian and items for development of European standards at the different stages according to the CEN/CENELEC programmes. It was open for updating and supplementing.

76 Technical Committees (TC) and 13 Expert Working Groups (EWG) worked actively in 2016. Regarding the technical bodies, the following changes were made and approved by BDS/BTN decisions:

- Restructuring of EWG 15 „Project, programme and portfolio management“ in TC 106 „Project, programme and portfolio management“ with a scope development of standards in the area of project and programme management, including portfolio management.
- Disbanding of EWG 7 “Event Management” following the disbandment of CEN/TC 375 and of ISO/TC 237 and ISO/TC 250 international project committees.
- Disbanding of EWG 17 “Care services for cleft lip and/or palate” following the disbandment of CEN/TC 424 European committee.

One of the main BDS activities in the past year was the development of standards at national level, primary in support of the national legislation and in cooperation with the executive authorities. For a consecutive year, as a result of cooperation with the Ministry of Regional Development and Public Works (MRDPW) and related to the implementation of Regulation (EU) No 305/2011 of the European Parliament and of the Council on construction products, national annexes to Bulgarian standards were developed and harmonized. These annexes implement harmonized European standards for construction products that establish the national requirements for determining the performance of the essential characteristics in relation to the intended use of these products.

More detailed information is provided below.



IMPLEMENTATION OF THE WORK PROGRAMME FOR STANDARDIZATION BY SECTORS

The activities of the national work bodies (BDS/TC and BDS/EWG) are performed by sectors in accordance with the classification of the European standardization organizations CEN and CENELEC, as follows:

Sector 1: Standards in the field of services and fundamental standards

(CEN Sector A - Services, Sector F - Fundamental standards)

Sector 2: Healthcare, environmental and medical equipment

(CEN Sector S - Health, environment and medical equipment)

Sector 3: Building and constructions

(CEN Sector B - Building and construction)

Sector 4: Machinery, transport, lifting equipment and packaging

(CEN Sector I - Mechanical engineering and Sector T - Transport, mechanical handling and packaging)

Sector 5: Metallic and non-metallic materials

(CEN Sector M - Metallic materials and Sector N - Nonmetallic materials)

Sector 6: Chemistry, food and products for household and leisure use

(CEN Sector C - Chemicals, chemical engineering and food products and Sector H - Products for household and leisure use)

Sector 7 – General electrotechnical standards, Electronics, Electrotechnical engineering, energy standards, standards in telecommunications and Information technology

(CENELEC/Sector U - General electrotechnical standards, Sector V - Electronic engineering, Sector W - Electrotechnical engineering, ETSI and CEN/Sector Z - Information technology)

Highlights in 2016:

Sector 3

Two Bulgarian national standards were developed in 2016, that were revised editions as a result of performed periodic review in the scope of TC 4 „Cement, lime and gypsum” and TC 5 „Concrete and mortars”. Nine national annexes to Bulgarian standards that implement harmonized European standards to Regulation (EU) No 305/2011 on construction products were also developed. The developments were related to the updating of the national annexes following the publication of new editions of the European standards.

National requirements to declare the performance of construction products depending on the intended use were also agreed. The national requirements refer to wood based products and elements for timber structures (**TC 33** „Forestry, wood, furniture technology and industry”); waterproofing systems/assemblies (**TC 61** „Insulation of buildings and building equipment”) and hydraulically bound materials (**TC 68** „Road engineering”). The work on the development of the national applications and the agreement on the national requirements was performed under contract No ПД-02-29-81/13.04.2016 between MRDPW and BDS.

Sector 4

According to the contract with MRDPW, a national annex to BDS EN 13240:2006 implementing a harmonized European standard to Regulation (EU) No 305/2011 on construction products was developed in this sector also with the purpose Annex NA.ZA to be included in the national annex.

National requirements in the scope of **TC 70** „Railway Transport” (jointly with TC 5 „Concrete and mortars”) to declare the performance of the prefabricated concrete and reinforced sleepers and bearers on the intended use were also agreed.

In addition, the basic standards containing requirements for elevators with a translation into Bulgarian were implemented:

- **BDS EN 81-20:2014** *Safety rules for the construction and installation of lifts - Lifts for the transport of persons and goods - Part 20: Passenger and goods passenger lifts*
- *and BDS EN 81-50:2014* *Safety rules for the construction and installation of lifts - Examinations and tests - Part 50: Design rules, calculations, examinations and tests of lift components.*

Sector 5

According to the contract with MRDPW national requirements to declare the performance of constructional products depending on the intended use were also agreed in this sector. The national requirements were in the scope of **TC 17** „Ferrous metallurgy“, referring to steel products for the reinforcement of concrete and for metal products and metal construction elements.

Sector 6

4 national annexes (in the scope of **TC 67** „Petroleum products and lubricants“ and **TC 81** „Plastics“) to Bulgarian standards, implementing harmonized European standards to Regulation (EU) No 305/2011 on construction products were developed under the contract with the MRDPW. The developments were related to the updating of national annexes following the publication of new editions of European standards. National requirements (in the scope of **TC 81** „Plastics“) to declare the performance of mechanical fittings for plastics pressure piping systems were also agreed.

Sector 7

BDS, as a national standards body, acts as a National Electrotechnical Committee (NEC) in this sector. In this respect, 46 drafts of documents were voted in 2016 in the following areas:

- *electromagnetic compatibility (EMC),*
- *nanotechnologies*
- *and IECCE (IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components).*

Summary

The total number of draft European standards and standardization documents voted by BDS in 2016 is provided in the table below:

Voted draft standards according to the stage	CEN	CENELEC
Public enquiry	797	60
Public enquiry and vote	97	443
Formal vote	798	346
Systematic review	407	–
Total	2 099	849

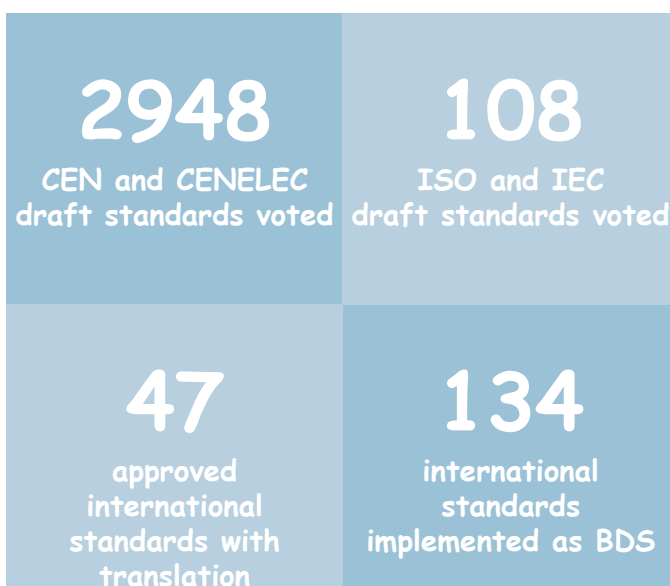
A systematic review of **399** BDS was performed in 2016 for the maintenance of updated fund of Bulgarian standards and as a result some Bulgarian standards were withdrawn due to obsolescence, while others were subject to revision for updating.

Annual activity report 2016

Related to BDS membership in the international organizations for Standardization (**ISO and IEC**) in 2016 it could be summarized:

- *BDS participated as an active member in **23 ISO/TC, 4 ISO/PC, 43 ISO/TC/SC, ISO/CASCO, ISO/COPOLCO and ISO/DEVCO.***
- *Regarding the International Electrotechnical Commission (**IEC**) BDS participated as an active member in **2 IEC/TC and 2 IEC/TC/SC.***

The total number of draft ISO and IEC standards voted by BDS in the past year was **108**. TCs approved **47** international standards with translation in Bulgarian; **134** international standards were implemented as BDS in one of the official languages in 2016.



IMPLEMENTATION OF ACTIVITIES UNDER 2016 ACTION PLAN

Enhancement of relations with state authorities

Pursuant to the tasks for cooperation with the executive authorities BDS experts performed terminological and linguistic editing of Bulgarian language versions of draft legislative acts, elaborated opinions on draft legislative acts and answers to inquiries to the following executive authorities:

- *Ministry of Agriculture and Food*
- *Ministry of Economy*
- *Commission for Consumer Protection*
- *Ministry of Transport, Information Technology and Communications*
- *Ministry of Environment and Water*

BDS experts also participated with comments in working groups for the development of technical regulations related to the application of standards at the following authorities:

- *Ministry of Regional Development and Public Works*
- *Ministry of Agriculture and Food*
- *Ministry of Health*

New Information Centres on Standardization at higher educational institutions

The enhancing of the cooperation between BDS and the higher education institutions aiming at promoting the standards led in 2016 to the opening of new four Information Centres at the following higher education institutions:

- *Sofia University „St. Kliment Ohridski“*
- *University of Architecture, Civil Engineering and Geodesy (UACEG) in Sofia*

- *Technical University of Gabrovo*
- *University of Economics - Varna.*

These centres provide for students and lecturers free access for reading standards in various areas.

Information Centre at the University of Architecture, Civil Engineering and Geodesy (UACEG) in Sofia



Seminars and trainings organized by BDS

Seminar on How to apply the new Standard for Management systems for private security operations – ISO/TS 18788:2015



Seminar on the national requirements for the including constructional products in constructions



Seminar organized to explain the changes, philosophy and new requirements of the fifth edition of ISO 9001:2015





*Training on BDS EN ISO 8015:2011.
Geometrical product specifications (GPS)
- Fundamentals - Concepts, principles and
rules, organised at the request of a company
operating in the field of mechanic engineering*

*The seminar with international participation
on „Medical tourism - scope and good
practices“ was attended by leading specialists*



*The participants in the seminar on
„Requirements for ecodesign and labeling
for energy efficiency of household electrical
appliances“ were informed on the updated
legislation in this field*



The participants in the seminars were offered the opportunity to purchase standards related to the topic at discount prices.

BDS AS A HOST OF ANNUAL MEETINGS OF EUROPEAN AND INTERNATIONAL TECHNICAL COMMITTEES

European Cleft Guidelines meeting (5 July, 2016)

A meeting initiated by the European Cleft Organization gathered top clinicians from Bulgaria, Greece, Serbia, England, Spain and France to discuss implementation of European guidelines on early care services for babies born with cleft lip and/or palate in countries where there is no established national legislation in the field. The aim of the meeting was to define the actions and strategies for creating favorable conditions to promote the implementation of the recommendations contained in CEN/TR 16824:2015 in countries where the cleft lip and palate protocols are not in place.



Plenary meeting of CEN/TC 228 „Heating systems and water based cooling systems in buildings“ (12-13 October 2016)

The 28th Plenary Session of CEN/TC 228 „Heating systems and water based cooling systems in buildings“ and the meeting of CEN/TC 228/WG 4 „Calculation methods and system performance and evaluation“ were organized by BDS/TC 41 „Heating, ventilating, air-conditioning and cleaning equipment“ and BDS/TC 43 „Refrigerating and cryogenic equipment“. 38 experts from 14 countries - England, Belgium, Bulgaria, Germany, Denmark, Italy, Malta, the Netherlands, Slovakia, Finland, France, Croatia, the Czech Republic and Switzerland participated in the events.



Meeting of ISO/TC 228/WG 2 „Health tourism services“ (10-11 November 2016)

Experts from Bulgaria, Great Britain, Germany, Austria, Spain and Tunis, a representative of the European Spas Association (ESPA) and a representative of Small Business Standards (SBS) attended the meeting. Experts from BDS/TC 89 „Tourism services“ participated on Bulgarian part. The main discussions were focused on the comments submitted to the draft ISO/NP 21426 „Tourism and related services. Medical spa. Service requirements“.



BDS PARTICIPATION AT EUROPEAN AND INTERNATIONAL LEVEL

As a member of the European and international standardization organizations BDS participates in the annual Assemblies of these organizations, in the meetings of the Technical Boards of the European organizations, in annual meetings of the European standardization working bodies and in other events of interest.



BDS representatives participated in the following events in 2016:

CEN and CENELEC Annual Meeting and General Assemblies (7-8 June 2016)

The meeting, held in Skopje, Macedonia, hosted by the Standardization Institute of the Republic of Macedonia, was attended on Bulgarian part by Mrs. Iren Dabizheva, Managing Director, Mr. Asen Georgiev, member of BDS Governing Board and member of the CENELEC CA, Mrs. Rositsa Georgieva, Director of Publishing activities, sales and services Directorate. The activity reports and financial reports for 2015 were approved and the draft budgets for 2017 were adopted.



80th General Meeting of the International Electrotechnical Commission (IEC) (October 2016, Frankfurt, Germany)

The Chairman of BDS Governing Board Ivelin Burov participated in the IEC official event. The organizer for the seventh time was the IEC German National Committee.

Participation in the Technical Boards of the European standardization organizations CEN and CENELEC

BDS delegated representatives participate regularly in the meetings of the Technical Boards of the European standardization organizations where their activities are discussed organized and coordinated.

CEN Technical Board

BDS representative participated in the 79th and 80th meetings of CEN Technical Board (CEN/BT) in February and September 2016, as well as in a joint meeting of CENELEC/BT and CEN/BT. Several major topics were discussed at the meetings: reduction of development time, the ISO procedure for the so-called „minor revisions“ and their impact on the process at CEN, the incorporation of A-deviations in the periodic review process, as well as strategic and general issues.

CENELEC Technical Board

BDS representative participated in the 152nd, 153rd and 154th meetings of the CENELEC Technical Board in February, May and September 2016, as well as in a joint meeting of CENELEC/BT and CEN/BT. CENELEC/BT discussed and adopted the updated action plan and the changes in the voting rules of the Internal Rules, Part 2 in accordance with the Lisbon Treaty, approved the development of a guidance for the proposed new edition of CENELEC Guide 13

„IEC - CENELEC Agreement on Common planning of new work item and parallel voting“, and discussed strategic issues and policies, technical and procedural issues.

At the joint CENELEC/BT and CEN/BT meeting the progress was noted on the implementation of the decisions of both BTs about the time for development – management of projects.

Participation of BDS representatives in annual meetings of European and international technical committees

Participation in a plenary session of CEN/TC 136/WG 2 „Fitness Centres“

BDS/TC 88 „Sport and equipment for sport“ representative took part in the plenary session of CEN/TC 136/WG 2 „Fitness Centres“ held in March 2016 in Berlin, Germany. The draft of „Fitness Centers - Requirements for Equipment and Operation“ - code of conduct, drug abuse/anti-doping, noise levels, lighting, risk assessment, surveillance“ was discussed at the meeting.

Participation in a plenary meeting of CEN/TC 234 „Gas Infrastructure“ and in a meeting of Gas Sector Forum Gas

Representatives of BDS/TC 60 „Gas Infrastructure“ participated in a plenary meeting of CEN/TC 234 „Gas Infrastructure“ in the spring of 2016 in Paris, France. Main topics of the meeting were updating of standards in the area of natural gas, standardization in the use of hydrogen by a research group and updating of the terminology used and its inclusion in standards in the area of the gas infrastructure.

Participation in plenary meetings of CEN/TC 155 „Plastics piping systems and ducting systems“

Representatives of BDS/TC 81 „Plastics“ participated in the 59th and 60th plenary meetings of CEN/TC 155 „Plastics piping systems and ducting systems“ held in Helsinki, Finland in May 2016 and in Athens, Greece, in November 2016. More important topics of the discussions were related to the case of the incorporation of international standards for testing methods in product standards without being implemented as European standards; the establishing of „weighted“ vote on draft standards under the Lisbon Treaty; the work on the revision of the series of gas supply standards, etc.

Participation in a plenary meeting of ISO/TC 228 „Tourism and related services“

The Chairman of BDS/TC 89 „Tourism activities“ took part in the 11th meeting of ISO/TC 228 „Tourism and related services“ and in the meetings of the working groups held in Malaysia in May 2016. BDS representative declared the Bulgarian interest in finalizing the standard „Medical Spa“ in view of the available mineral resources and the interest of the business in implementing such a standard.



Participation in a plenary meeting of ISO/TC 228 „Tourism and related services“

Participation in a plenary meeting of CEN/TC 295 „Residential solid fuel burning appliances“

Representatives of BDS/TC 8 „Gas equipment, gas cylinders, fittings for gas equipment, household equipment for solid and liquid fuel“ participated in a plenary meeting of CEN/TC 295 „Residential solid fuel burning appliances“ in November 2016 in Paris, France, where a wide range of issues were discussed, including the Ecodesign regulations, emission measurement methods, work on new drafts, etc.



Fifth Balkan Conference on Standardization

Fifth Balkan Conference on Standardization (14-15 June 2016)

The conference was held in Belgrade, Serbia and was hosted by the Institute for Standardization of Serbia. Over 20 representatives of 11 national standardization bodies from the Balkan countries attended the event. BDS was represented by Iren Dabizheva, Managing Director and Rositsa Georgieva, Director of Publishing activities, sales and services Directorate. The main topic of the event was „Sustainability of National Standardization Bodies“. All standardization bodies presented their best practices in various areas of activities. BDS participated with two presentations, and in addition to the predefined themes, the practice of establishing Information Centres on Standardization at universities was also presented.

PROJECT IMPLEMENTATION

Framework Partnership Agreement for translation of European standards in the Community languages

The implementation of the two-year Framework Partnership Agreement for translation of European standards in Bulgarian under a programme funded by the Directorate General „Internal Market, Industry, Entrepreneurship and SMEs“ of the European Commission (EC) continued in 2016. The programme is a part of the EC measures to support the competitiveness of the European economy and to raise SMEs' awareness as well as to facilitate access to European standards in national language for manufacturers, local industrialists, testing laboratories and the national authorities. 114 European standards in various areas were implemented with Bulgarian translation in 2016 within the agreement.

A new project proposal for participation in the following Framework Partnership Agreement for translation of European standards in the community languages for the period 2017 – 2018 was elaborated and submitted in August 2016.



ISTRA - International Standards training in VET for promotion of market relevant education

The Bulgarian Institute for Standardization participates in the implementation of a project funded by Erasmus+ programme of the European Commission, Key Action 2 „Cooperation for innovation and the exchange of good practices - Strategic Partnerships“ and managed by the Human Resources Development Centre (HRDC) – the Programme's National Agency for Bulgaria.

The main objective of ISTRA project is the development and piloting of two sets of innovative training approaches and contents for VET and C-VET training on two widely applicable series of standards (ISO/IEC 27000 and ISO 31000). The standards selected for training can be applied in practice in a wide range of organizations, regardless of their size, nature or organizational specifics and they are ones of the most widely used standards internationally.

The educational materials about the standards will be developed by experts from the national standardization bodies of the countries involved in the project. These materials will be integrated in e-learning courses and will be piloted in Virtual Learning Environment (VLE). The VLE will be developed through the use of cutting-edge ICT-based educational technologies and innovative approach towards delivering theoretical knowledge and practical skills in applying standards in various spheres.

The kick-off project partner meeting was held at the Bulgarian Institute for Standardization in November 2016 and was attended by representatives of all participating organizations. The partners agreed on a detailed work plan for the first year with specific tasks, deadlines and responsibilities.

The project is implemented in partnership between Burgas Free University (coordinator), Bulgarian Institute for Standardization (BDS), Latvian College of Culture, Bureau of Standards of the Standardization, Accreditation and Metrology Centre of Latvia (LVS), Technological High School „George Bibescu“, Craiova, Romania, Secondary School of Technical and Electrical Engineering, Presov, Slovakia and Vocational Trade School, Burgas.




The kick-off project partner meeting was held at the Bulgarian Institute for Standardization

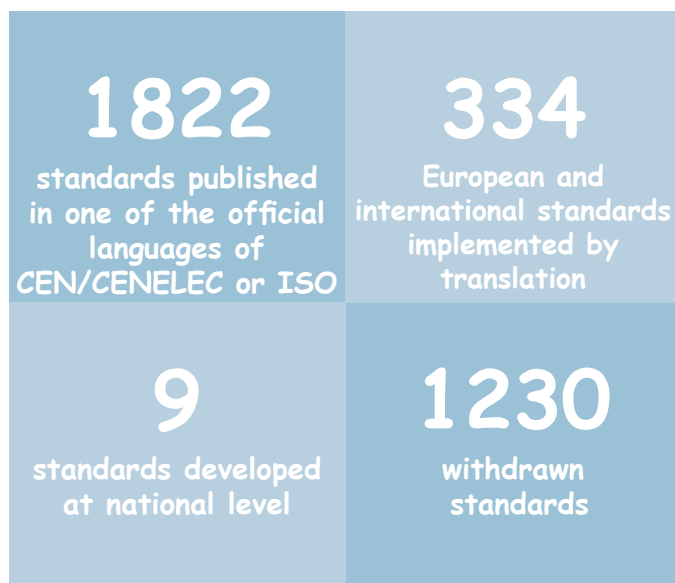
PUBLISHING OF STANDARDS AND OTHER PUBLICATIONS

A total of **343** standards were published in 2016, 334 of them were European and international standards and standardization documents, implemented by translation in Bulgarian. **Nine** standards developed at national level were published, including 7 national annexes to European standards and two BDS (reviewed and updated publications, covered by BDS/TC 4 and BDS/TC 5).

A total of **1822** standards were published in one of the official languages of CEN/CENELEC or ISO. The number of withdrawn standards due to obsolescence is a total of **1230**.

Октомври 2016

 БДС БЪЛГАРСКИ ИНСТИТУТ ЗА СТАНДАРТИЗАЦИЯ	БЪЛГАРСКИ СТАНДАРТ	БДС EN ISO 13485
	МЕДИЦИНСКИ ИЗДЕЛИЯ СИСТЕМИ ЗА УПРАВЛЕНИЕ НА КАЧЕСТВОТО Изисквания за целите на нормативните актове (ISO 13485:2016)	
ICS 03.120.10; 11.040.01		Заменя БДС EN ISO 13485:2012
<p>Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)</p> <p>Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2016)</p> <p>Dispositifs médicaux - systèmes de management de la qualité - Exigences à des fins réglementaires (ISO 13485:2016)</p> <p>Европейският стандарт EN ISO 13485:2016 има статут на български стандарт от 2016-04-18.</p> <p>Този стандарт е официално издание на български език на европейския стандарт EN ISO 13485:2016.</p> <p>Преводът е направен от Българския институт за стандартизация. Изданието има същия статут като изданията на официалните езици на CEN.</p> <p>Изданието на български език на този стандарт е одобрено от изпълнителния директор на Българския институт за стандартизация на 2016-10-31.</p>		
<small>© BICS 2016. Българският институт за стандартизация е носител на авторските права. Всичко възпроизвеждане, включително и частично, е възможно само с писаното разрешение на БИС. 1707 София, кв. „Изгрев“, ул. „Личевар Станев“ № 13. www.bis.bg.org</small>		<small>Национален ИР за нормативни БДС EN ISO 13485:2016</small> <small>Нормативен ур. 2</small> <small>с. 72 стр. от EN ISO</small>



Statistics

The table and the graph below illustrate the information on the implemented standards in 2016 by types.

Type of standards	Number
BDS	9
ISO	148
ISO/IEC	10
IEC	2
EN	934
EN ISO	435
HD	9
ETSI	150
Standardization deliverables of CEN, CLC, ISO, ETSI	161
Total	1 858

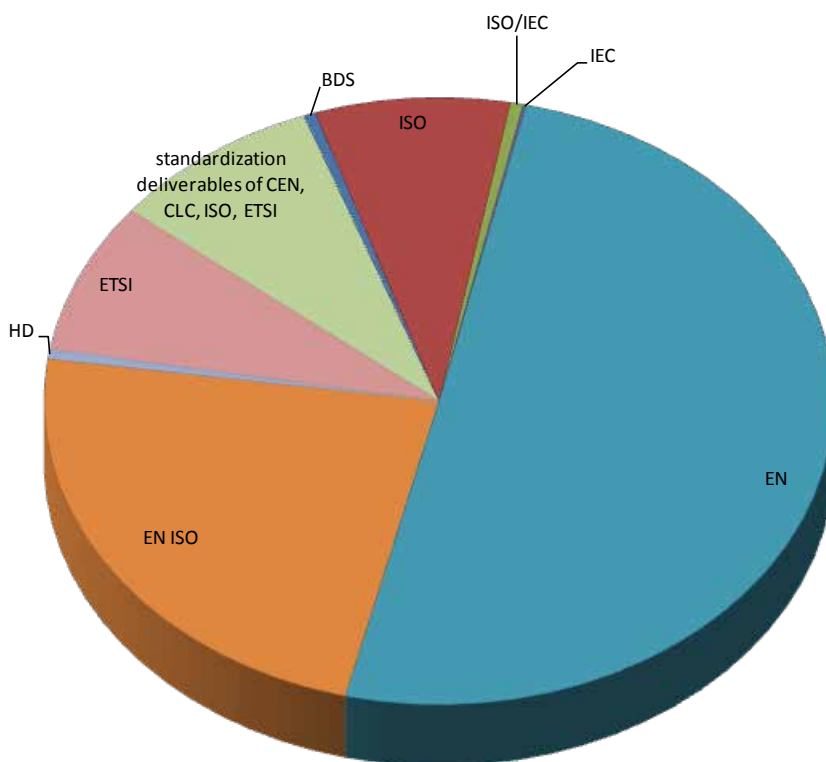
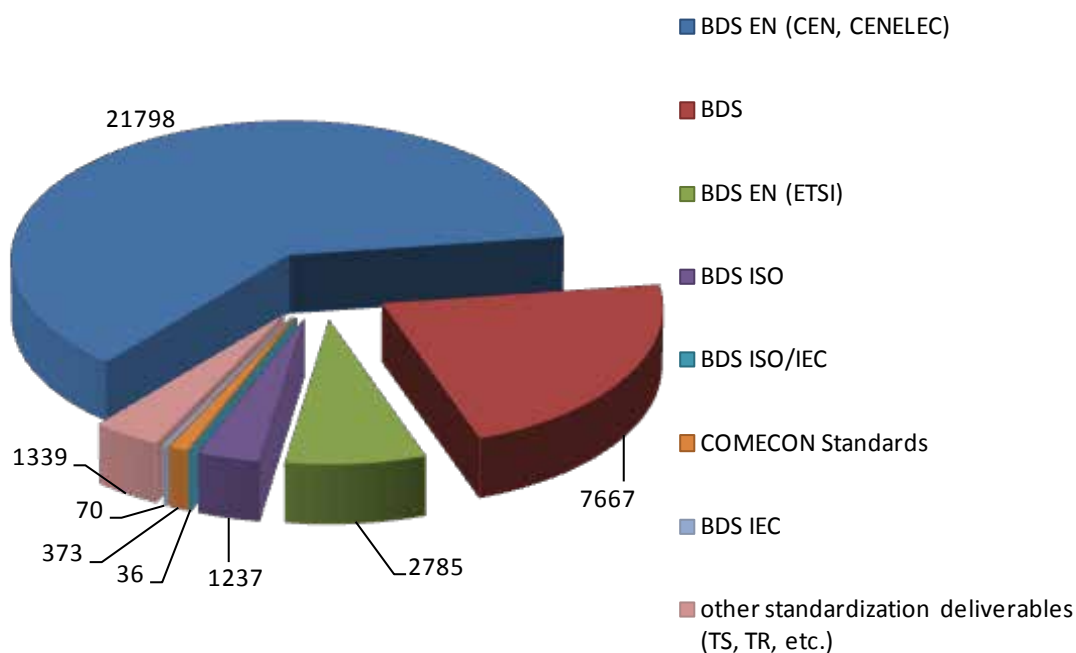


Chart of the implemented standards in 2016 by types

What the national fund of Bulgarian standards comprises in 2016 is shown in the chart below:



National fund of standards by the end of 2016

Comparison data of the fund of Bulgarian standards for the three consecutive years is presented in the table below:

Type of national standards	2014	2015	2016
BDS EN (CEN, CENELEC)	20 954	21 374	21 798
BDS	7 902	7 752	7 667
BDS EN	2 557	2 637	2 785
BDS ISO	1 192	1 167	1 237
BDS ISO/IEC	27	28	36
COMECON standards	396	383	373
BDS IEC	79	68	70
Other standardization deliverables (TR, TS, etc.)	1 196	1 246	1 339
Total	34 303	34 655	35 305

Other publications

Pursuant to the tasks of the Action Plan for 2016 and to promote the standardization activities, BDS has published 4 issues of the online BDS Compass magazine on the following topics:

- Issue 1 Textile
- Issue 2 Windows
- Issue 3 Water quality
- Issue 4 Risk management

The total number of reviews at BDS website (3626 times) shows that the magazine has its audience and achieves its goals.

БДС Компас

Издание на Българския институт за стандартизация
Брой 1
януари – март 2016

ТЕКСТИЛ



- ✓ Десет години БИС – публично-правна организация
- ✓ АNEC – гласът на европейските потребители



Collections of standards

BDS extended the products offered in 2016 and issued 3 new collections of standards in electronic format offered at preferential prices:

- Collection "Conformity assessment"
- Collection "ISO 31000 Risk management – basic standards"
- Collection "ISO 55000 Asset management".

Thus, the total number of collections offered by BDS reached 22.



BDS issued 9 **electronic newsletters** in 2016, which were sent to BDS members and to business and branch organizations for distribution among their members. The electronic newsletter contains up-to-date information about standards - standardization news, popular, new and important standards, collections of standards, seminar information, etc. A new section in the newsletter "SME and their participation in the standardization process" was created in 2016. News addressed to SME representatives are published in this section.

At the request of the Chamber of Architects in Bulgaria, BDS developed a **guide for architect – designers** in 2016. It includes selected information on harmonized standards for construction products related to architectural design. The guide is distributed by the Chamber of Architects among its members.

INFORMATION SERVICES AND SALES. NATIONAL INFORMATION CENTRE

Information on Bulgarian, European, international and foreign standards and standardization deliverables is provided by BDS Information Centre.

BDS offers the following information services:

- *bibliographical references on Bulgarian, international, European and foreign standards and standardization documents*
- *field-specific and thematically-focused references*
- *elaboration of references on the actuality of standards and standardization documents*
- *replies to customers inquiries.*



In 2016, 736 thematic and bibliographical references were prepared, information on 2022 documents was provided, 6 references on the actuality of Bulgarian standards and 72 references on the actuality of international standards were prepared; 114 replies to customers' inquiries in the standardization area were delivered by the Information Centre.

736 thematic and bibliographical references	information on 2022 documents was provided
78 references on the actuality of standards	114 replies to customers' inquires in the standardization area

***BDS provided a new service
“Subscription on actuality of Bulgarian standards”
to its customers in 2016***

BDS provided a **new service “Subscription on actuality of Bulgarian standards”** to its customers in 2016. Over the period of one year the customers receive monthly information on the package of standards they work with or are of their interest – status, language that they are available in, new editions published, amendments and corrigenda. The use of this service assure customers that they are working with the actual editions of the standards; saves time and means of seeking for possible changes of standards; reduces the risk of using invalid or incomplete standards edition.

The e-mailing to customers, who have purchased more popular standards, continued in 2016 informing them on important changes related to those standards:

- *Publication of amendment – A1, A2,*
- *New edition of the standard,*
- *New edition of the standard, including amendment (EN+A1),*
- *Publication of standard with Bulgarian translation,*
- *Publication of national annexes,*
- *Publication of corrigenda of standards.*

E-mails about 218 standards were sent to 3206 customers in total.

The library at the Information Centre provides the customers with opportunity to find the information they need and to become familiar with the texts of standards and standardization documents, including all European and international standards, and foreign standards, which BDS offers under bilateral contracts. 285 BDS customers have benefited of this service and 1007 documents were provided to them in the past 2016 year.

The customers, who want to familiarize themselves with the text of standards before they purchase them, use the information service provided for online reading of standards. The most commonly used online reading was “5 standards for 5 days” and 422 customers (89,8% of all) used it in 2016. The total number of read standards is 2177.

422

customers used
online reading

2177

read standards

Sales of standards

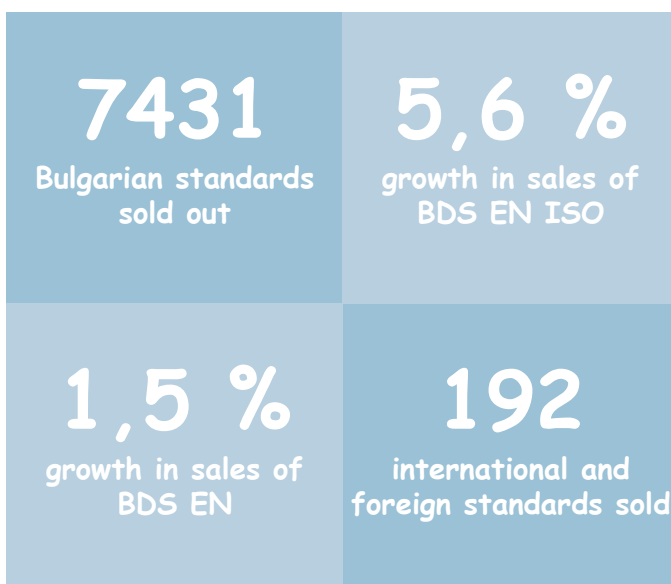
The total number of Bulgarian standards sold out in the past year was 7431, which is at the level of sales in 2015 (7470).

Growth of 5,6% was observed in the sales of **BDS EN ISO**. The best selling standards which account to 12,6% of the total sales are: **BDS EN ISO 9001:2015** *Quality management systems. Requirements (ISO 9001:2015)*, **BDS EN ISO 14001:2015** *Environmental management systems. Requirements with guidance for use (ISO 14001:2015)*, **BDS EN ISO 9000:2015** *Quality management systems. Fundamentals and vocabulary (ISO 9000:2015)*, **BDS EN ISO 17100:2015** *Translation Services. Requirements for translation services (ISO 17100:2015)*. The new editions hold a share of 14,3% of the sales in this group.

Growth of about 1,5% was registered in the sales of **BDS EN**, and the new editions represent 8,1% of the sales in this group.

2,8% is the decline in sales of **BDS ISO**. The demanded standards in this group represent 1,6% of total sales: **BDS ISO 31000:2011** *Risk management. Principles and guidelines*, **BDS ISO 2909:2015** *Petroleum products. Calculation of viscosity index from kinematic viscosity*, **BDS ISO/IEC 27001:2014** *Information technology. Security techniques. Information security management systems. Requirements*. The new editions represent 7,1% of the sales in this group.

Bigger decrease is observed in the sales of national standards **BDS** - 13%. The largest share of sales belongs to **BDS 14:2010** *Bulgarian kashkaval* – 13 sales and **BDS 15:2010** *Bulgarian white cheese in brine* – 11 sales.



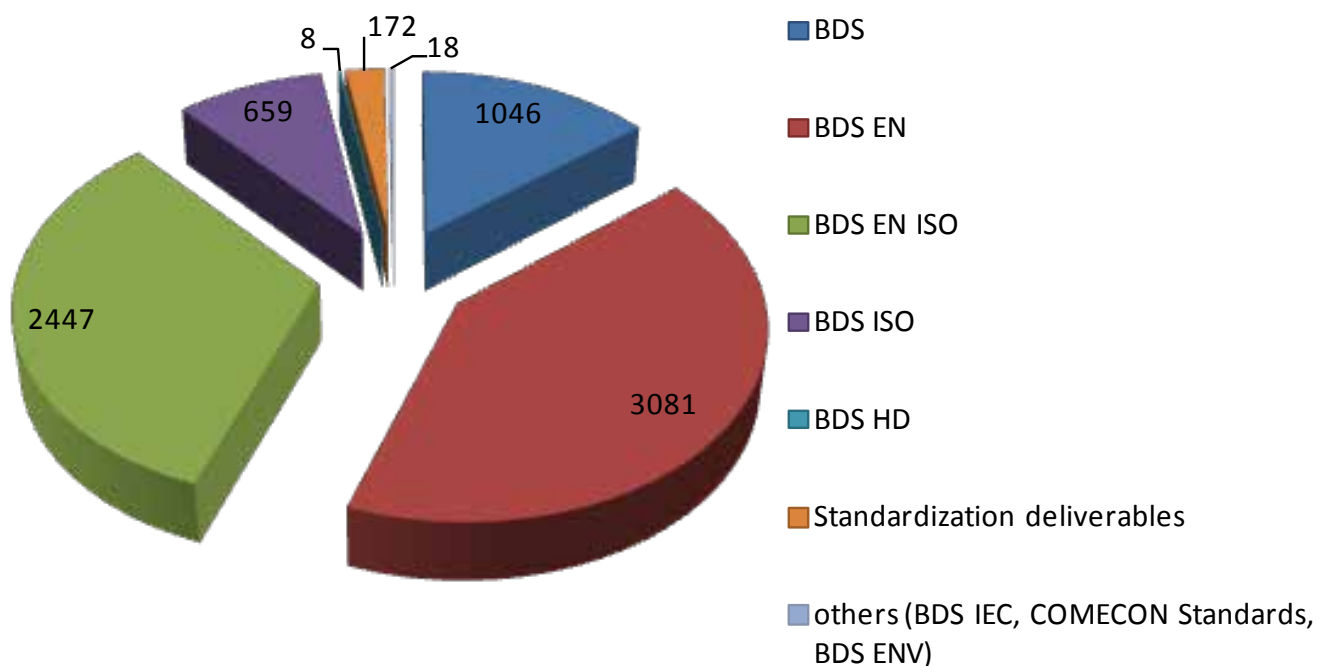
The demand for the following collections of standards is rising in 2016:

- "ISO 9000 Quality management systems – basic standards" – 34 sales.
- "ISO 9000 and ISO 10000 Quality management systems" – 28 sales.

There is also significant interest in the new collections:

- "ISO 31000 Risk management – basic standards" – 22 sales.
- "Conformity assessment - certification of management systems" – 11 sales.

The sales by types in the past year are illustrated in the graph below:



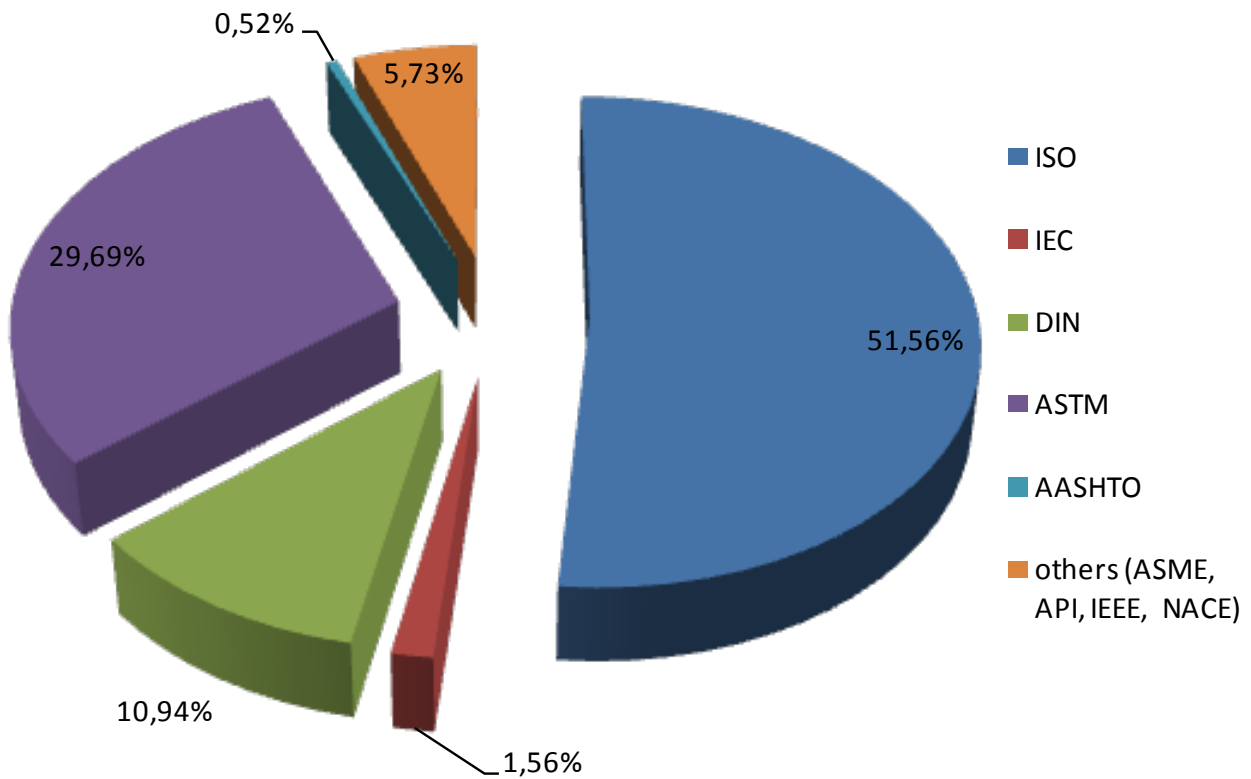
Bulgarian standards sold out in 2016 by types

Annual activity report 2016

The decline of 22% in sales of international and foreign standards, which was reported in 2015 continued in 2016. 192 documents of international and foreign standardization organizations were sold in total in accordance with BDS distribution agreements,

including: international (ISO, IEC), German (DIN), American (ASTM) and others (AASHTO, ASME, API, IEEE, etc.). This decline was observed in the two largest groups of standards: ISO – 22 % and ASTM – 33 %, while DIN has increased by 63,5%.

The proportion of these sales is given in the following chart:



International and foreign standards sold out in 2016

Information of the best-selling Bulgarian standards in 2016 is given in the following table:

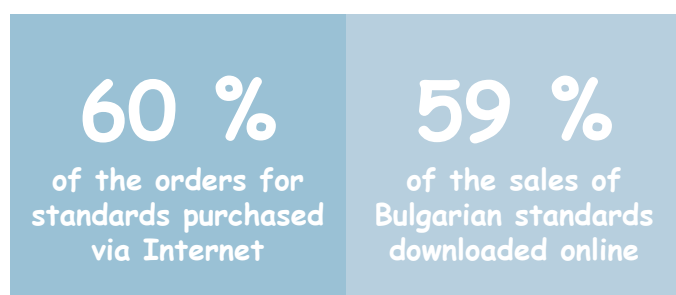
Standard	Number of sales
BDS EN ISO 9001:2015 Quality management systems - Requirements	416
BDS EN ISO 14001:2015 Environmental management systems – Requirements with guidance for use	151
BDS EN ISO 9000:2015 Quality management systems – Fundamentals and vocabulary	92
BDS EN 482:2012+A1:2015 Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents	26
BDS EN ISO 17100:2015 Translation Services - Requirements for translation services (ISO 17100:2015)	26
BDS EN ISO/IEC 17021-1:2015 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements	25
BDS ISO/IEC 27001:2014 Information technology – Security techniques – Information security management systems - Requirements	24
BDS ISO 31000:2011 Risk management – Principles and guidelines	23
BDS EN ISO 7027-1:2016 Water quality - Determination of turbidity - Part 1: Quantitative methods	21
BDS EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes	18
BDS EN 16636:2015 Pest management services - Requirements and competences	17
BDS EN ISO 50001:2011 Energy management systems - Requirements with guidance for use	16
BDS EN ISO 662:2016 Animal and vegetable fats and oils - Determination of moisture and volatile matter content	16
BDS EN ISO/IEC 17020:2012 Conformity assessment - Requirements for the operation of various types of bodies performing inspection	16

The largest number of sales in 2016 was realized in the following areas of standardization:

- *quality management and conformity assessment;*
- *risk management;*
- *environmental protection;*
- *information security;*
- *agricultural and food products;*
- *energy management.*

The continuously improved automated standardization and sales management system facilitates the customers and shortens the time to get the information they need, as a result of which:

- *the growth in the proportion of orders for standards purchased via Internet marks a steady upward trend – from 46,3% in 2013 to 48,1% in 2014, 54,67% in 2015 and 60% in 2016 out of the total number;*
- *the share of sales of Bulgarian standards downloaded online increases – from 53,5% to 59%, on CD decreases – from 32,3% to 30,7%, and those on paper copy decreases from 14,1% to 10,3%.*

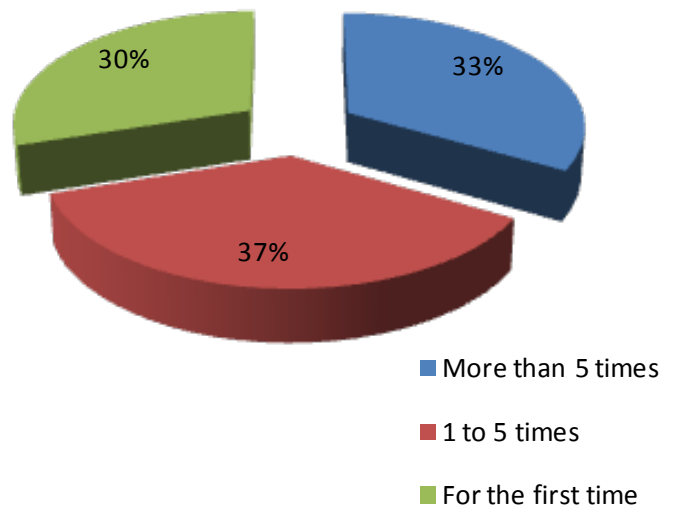


Customer satisfaction

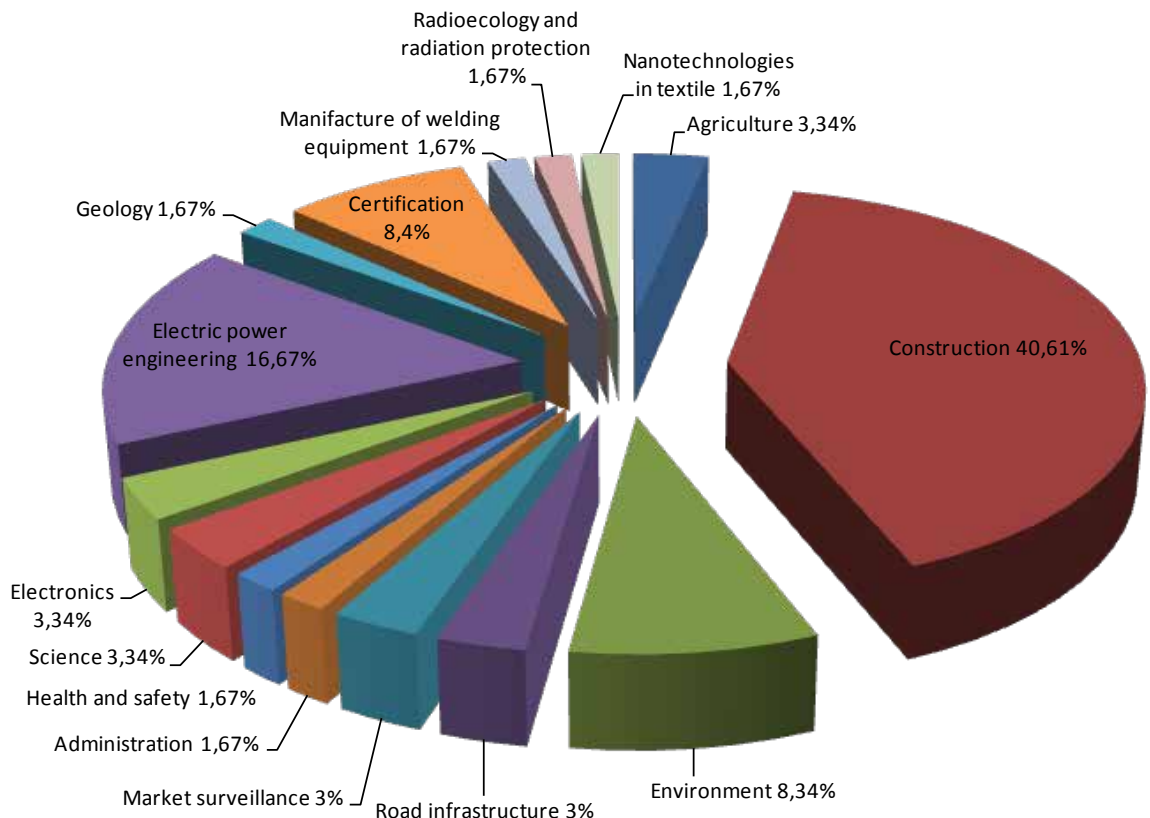
A marketing survey among BDS customers was carried out, which shows that the most important factor in selecting products and services is „benefit“ followed by „quality“ and „price“. 84% of customers are satisfied with the proposed collections of standards and the standards implemented by translation in Bulgarian. However, 4% of customers are not satisfied with the translations of standards, which also indicates the direction in which we should work to offer better quality products. It turned out that the majority of customers have information about the new services that are being offered. More than 90% of them know about the discounts offered, and are mainly informed by e-mails sent by BDS. 24% of customers always benefit from the discounts and only 8% have never benefited.

The main recommendations of customers are to continue to offer collections of standards and send information by e-mail, as well as to improve translations of standards through co-ordination between individual TCs.

**Answers to the question:
How many times have you used BDS
products and services?**



**Answers to the question:
You are engaged in the field of ..?**



BDS activities related to the EU membership of Bulgaria

Being a member of the European Union (EU) Bulgaria observes its engagement in implementing Regulation (EU) 1025/2012 of the European Parliament and of the Council for information exchange as well as the obligations under the Agreement with the World Trade Organization (WTO/TBT) to remove technical barriers to trade. The national Information Centre performs its obligation to provide information in the field of standardization in accordance with those documents.

Six draft standards, developed at national level were notified in 2016.

1 155 CEN and **402 CENELEC** national standards implementing European standards were notified through the Management Centre of CEN and CENELEC (CCMC).

At the same time BDS continued the regular sending of information on Bulgarian titles of European standards at draft stage and ratified document and harmonized standards for citation in EU Official Journal.

During the past year information was regularly provided on notifications of draft national standards under the Vilamoura procedure at CENELEC sent by the national committees. Information was provided to 27 inquires received from organizations in the country and abroad. Information was provided in due course to the state administration bodies according to the area of competence for submitted drafts of European standards at public enquiry stage.

1 155

notified
national standards
in CEN

402

notified
national standards
in CENELEC

FINANCING THE STANDARDIZATION ACTIVITIES

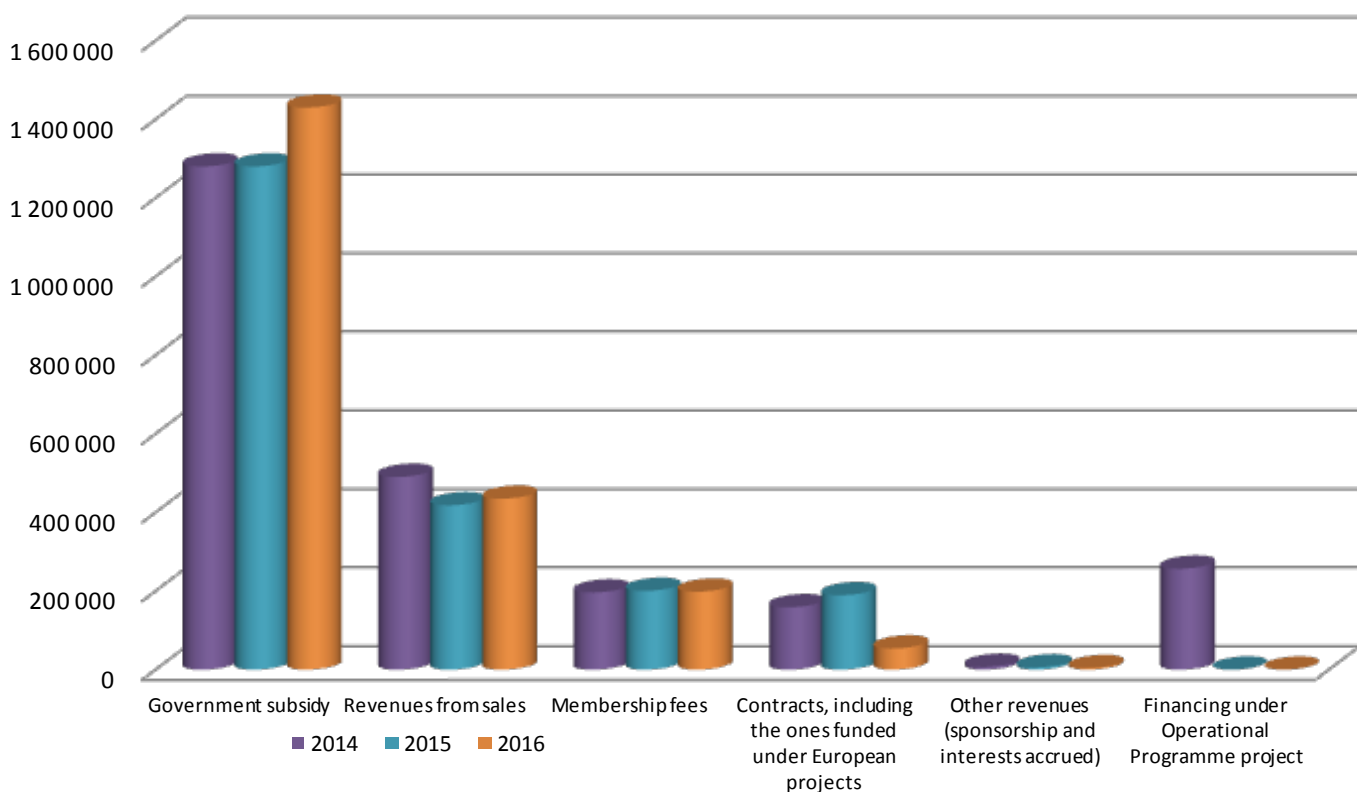
Revenues in 2016

Source of funding	BGN	%
Government subsidy	1 430 000	67
Revenues from sales	434 873	21
Membership fees	198 358	9
Contracts, including ones funded under European projects	53 851	3
Other revenues – sponsorship and interests	3 984	0
Total revenues	2 121 066	
Balance as of 01.01.2016	179 326	



Financing of the standardization activities in 2016 (BGN)

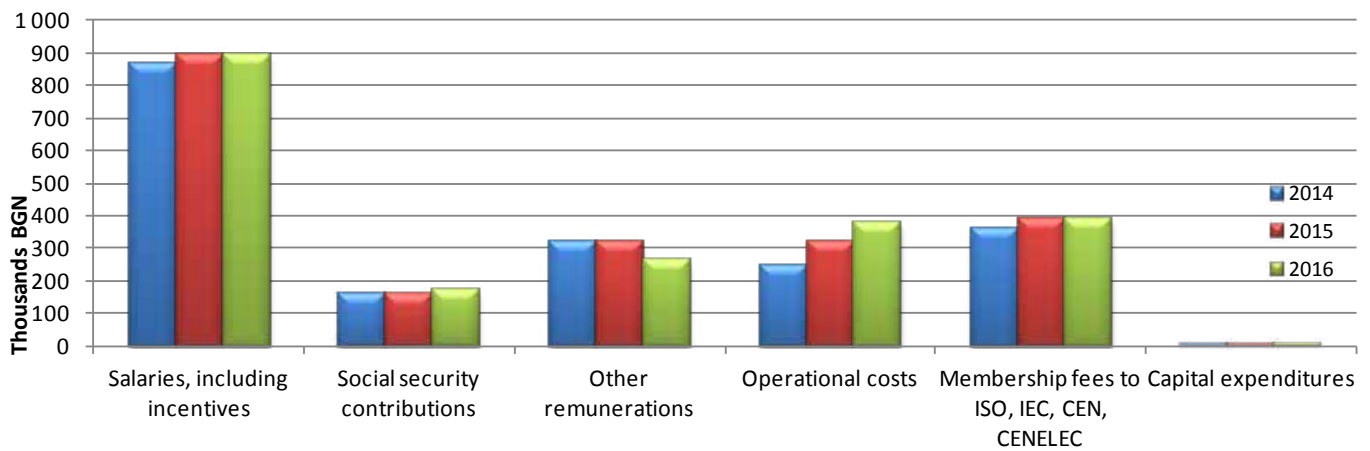
Source of funding	2014		2015		2016	
	BGN	%	BGN	%	BGN	%
Government subsidy	1 280 000	53	1 280 000	61	1 430 000	67
Revenues from sales	490 313	20	418 039	20	434 873	21
Membership fees	196 284	8	200 326	9	198 358	9
Contracts, including ones funded under European projects	158 549	7	189 367	9	53 851	3
Other revenues – sponsorship and interests	7 111	1	5 786	1	3 984	0
Financing under the “Competitiveness” Operational Programme project	256 690	11	0	0	0	0
Total revenues	2 388 947		2 093 518		2 121 066	
Balance funds as of 01.01 for the year	249 189		181 769		179 326	



Financing of the standardization activities in the period 2014 – 2016 (BGN)

Expenditures in 2016

Expenditures	BGN	%
Salaries, including incentives	897 630	42
Social security contributions	174 378	8
Other remunerations	266 145	13
Operational costs	381 098	18
Membership fees to ISO, IEC, CEN, CENELEC	392 439	19
Capital expenditures	7 840	0
Total costs	2 119 530	
Funds available at the end of the year	205 726	



Costs for 2014 – 2016 (BGN)

ADMINISTRATIVE CAPACITY

The competence and the experience of the employees of the Bulgarian Institute for Standardization are of great importance for carrying out the activities related to standardization. At the end of 2016 BDS has a staff of 70 people with no tendency to staff turnover. Over the past year, five new employees were engaged.

To be quickly and efficiently introduced in the specifics of BDS activities, each newly appointed employee has an individual training program prepared, tailored to the specific workplace that is executed under the direct guidance of the respective head of department/sector. The programme includes:

- *familiarization with the normative documents, objectives and principles of standardization*
- *familiarization with the processes of developing and approving the standards*

- *acquisition of practical skills related to pursuit the activity of the national standardization in the fields, determined for the employee concerned.*

An integral part of the introductory training is also an introduction to the current Quality Management System covering all work process related activities. In this way each employee can adapt easier and quicker to the working environment and the specifics of the work.

In order to increase and maintain the qualification, knowledge and skills of the long-term employees of the Bulgarian Institute for Standardization, internal trainings and briefings were carried out periodically during the year.

By maintaining the competence, the experience and the skills of its employees, the Bulgarian Institute for Standardization succeeds to meet the requirements of its partners and customers from all areas of economy, science and business.



Annual activity report 2016

Bulgarian Institute for Standardization

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