



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

IEC TC 62: Overview & Work Program

Norbert Bischof,

Secretary IEC TC 62, SC 62B and SC 62C

Presented by Nicole Denjoy

DITTA Vice-Chair

COCIR Secretary General

DITTA Workshop on International Standards

Florianópolis, , 12 Sept. 2016



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- IEC TC 62 Achievements in Q2/2016
- IEC TC 62 Work Program
- IEC TC 62 Forthcoming meetings



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中国医疗器械行业协会
China Association for Medical Devices Industry



Korea Medical Devices Industrial
Coop. Association

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INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)

Outline
IEC TC 62

The International Electrotechnical Commission (IEC) is a non-governmental organisation of Member Countries.

The IEC publishes International Standards and other publications for electrical, electronic and related technologies.

The stakeholders in IEC include industry, academia, regulators, users and consultants.

The International Standards Organisation (ISO) is a partner organisation of IEC. Both organisations follow a common set of rules and directives.



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IEC TC 62 SCOPE

Outline
IEC TC 62

Since **2011**, the scope of Technical Committee 62 of the IEC is :

*To prepare international standards and other publications concerning **electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment.***

*NOTE: This scope includes items that are also within the scopes of **other committees** and will be addressed through **cooperation**. Attention will **focus on safety and performance** (e.g. radiation protection, data security, data integrity, data privacy and environmental aspects) and will **contribute to regulatory frameworks**. Healthcare includes **medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living)**.*



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Outline IEC TC 62

- 29 Participating Countries
- 19 Observer Countries
- Secretariat: Germany
- 1285 experts in
- ~ 50 working groups with a total number of
- 2122 seats in
- 4 Subcommittees.
- 66 „harmonized standards“ European Union
- 75 „recognized standards“ FDA CDRH, USA
- 36 „recognized standards“ Health Canada



LEADERSHIP OF IEC TC 62

Outline
IEC TC 62

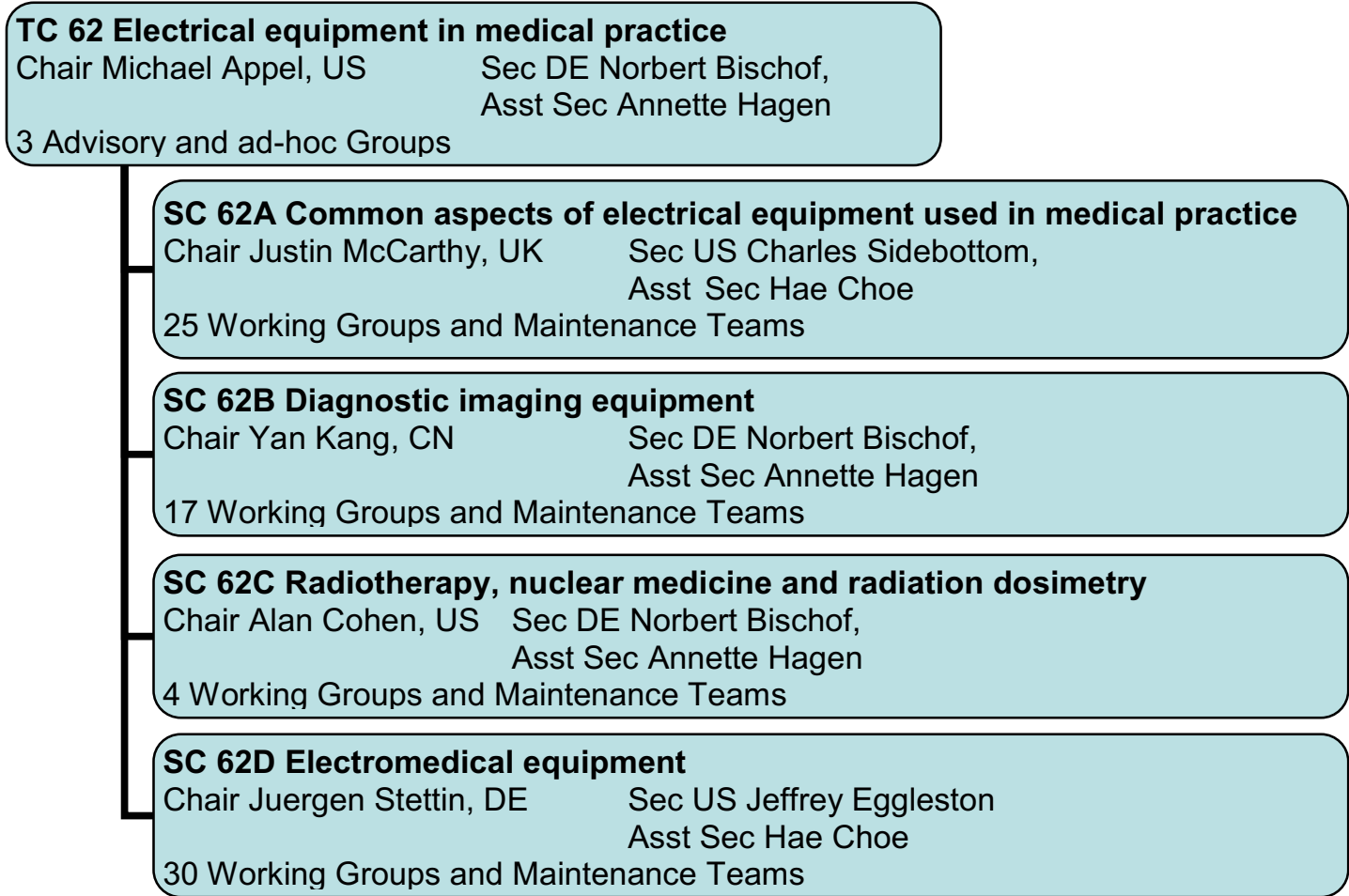


Figure 1 Organization Chart of TC 62 and Subcommittees (effective June 1, 2016)



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IEC TC 62: NEW PROJECTS Q2/2016

IEC TC 62 Achievements

Document	Project
62A/1096/NP	Health software and health IT systems safety, effectiveness and security - Foundational principles, concepts and terms
62A/1100/RR	IEC 62304 Ed 2: Health software - Software life cycle processes
62B/1003/RR	IEC 60601-2-63 Ed 1: Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
62B/1005/RR	IEC 60601-2-65 Ed 1 : Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
62B/1008/RR	IEC 60601-2-54 Ed 1: Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
62B/1011/RR	IEC 60601-2-43 Ed 2: Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
62C/645/NP	Dedicated Radionuclide Imaging Devices - Characteristics and Test Conditions - Part 1: Cardiac SPECT
62D/1349/NP	Medical electrical equipment - Part 2-xx: Particular requirements for the basic safety and essential performance of home light therapy equipment
62D/1354/RVN	ISO 81060-3 Ed 1: Non-invasive sphygmomanometers – Part 3: Clinical investigation of continuous non-invasive automated measurement type
Preliminary work item of SC 62C	IEC 62083 to cover the subject of the rejected work item on “Requirements of safety of external-beam radio-therapy systems including RTPS for a moving target”





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IEC TC 62: MILESTONES REACHED Q2/2016

IEC TC 62 Achievements

Document	Project
62B/1004/CDV	Amendment 1 to IEC 60601-2-63: Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
62B/1006/CDV	Amendment 1 to IEC 60601-2-65: Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
62B/1012/CDV	Amendment 1 to IEC 60601-2-43: Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
62D/1344/CDV	Amendment 1 to IEC 60601-2-4: Medical Electrical Equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
Document	Project
62A/1093/DTR	ISO TR 80002-2 Ed 1: Medical device software - Part 2: Validation of software for medical device quality systems
62A/1097/DTR	IEC TR 80001-2-9 Ed 1: Application of risk management for IT networks incorporating medical devices - Part 2-9: Application guidance - Guidance for use of security assurance cases to demonstrate confidence in IEC TR 80001-2-2 security capabilities
62A/1099/DTR	IEC TR 60601-4-1 Ed 1: Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy





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IEC TC 62: PUBLICATIONS Q2/2016

IEC TC 62
Achievements

25 new or revised Standards published

SC 62A: 3

SC 62C: 3

SC 62D: 19

No Standards withdrawn





IEC TC 62: EXAMPLE PUBLICATIONS Q2/2016

IEC TC 62
Achievements

SC	Publication reference	Title
62A	IEC TR 60601-4-2 Ed 1	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
62A	IEC TR 62366-2 Ed 1	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
62A	IEC TR 80001-2-8 Ed 1	Application of risk management for IT-networks incorporating medical devices - Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2
62C	IEC 60731:2011+AMD1:2016 Ed 3.1	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy
62C	IEC 60731:2011/AMD1:2016 Ed 3	Amendment 1 - Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy
62C	IEC 61303:1994/COR1:2016 Ed 1	Corrigendum 1 - Medical electrical equipment - Radionuclide calibrators - Particular methods for describing performance

Complete list available
upon request



At the meetings in Kobe November, 2015, IEC TC 62 developed a procedure for the future updates of the IEC 60601 series.

A two-step approach was taken.

The first step, “Amendment 2 to Edition 3 of IEC 60601-1”, is intended with restrictively selected modifications, and a publication date in **2019**.

The second step, “Edition 4 of IEC 60601-1” is intended to possibly include larger modifications, such as a **new architecture**, and a publication date around **2024**.



AMENDMENT 2 TO IEC 60601 EDITION 3

Work Program
IEC TC 62

For the first step, amendment 2, the SC 62A CAG has “restrictively” selected 160 modifications.

A couple of documents have been circulated in SC 62A:

Questionnaire	Results	Standard	Comments
62A/1077/Q	62A/1102/RQ	60601-1	67 pages
62A/1078/Q	62A/1103/RQ	60601-1-2	55 pages
62A/1079/Q	62A/1104/RQ	60601-1-6	51 pages
62A/1080/Q	62A/1105/RQ	60601-1-8	49 pages
62A/1082/Q	62A/1106/RQ	60601-1-10	48 pages
62A/1083/Q	62A/1107/RQ	60601-1-11	51 pages

These 160 modifications will be subject to the SC 62A meeting in Frankfurt, Germany



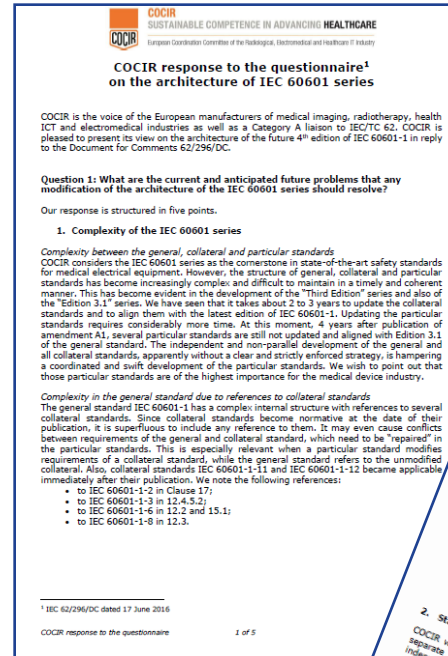


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EDITION 4 OF IEC 60601-1

Work Program
IEC TC 62

For Edition 4 of the IEC 60601-1, TC 62 has circulated a document for comments to its National Committees and to Liaison Bodies.





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SOFTWARE AND IT NETWORKS - SNAG AND JWG 7

Work Program
IEC TC 62

In dealing with **software** and the integration of medical devices with **IT-networks**, **IEC TC 62 2011 has established the Software and Networks Advisory Group (SNAG)**. This group is responsible for reviewing the scope and justification of proposals for new or maintenance work that originates from sources, other than National Committees or formal liaison organizations. The Group makes work recommendations to the TC/SC Officers on whether and how to allocate the work within TC 62 and about cooperation to be established with other committees or organizations.

IEC TC 62 has allocated work proposed by the SNAG to Joint Working Group 7 of its Subcommittee 62A and ISO TC 215 Health Informatics.



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IEC TC 62 FRANKFURT

Forthcoming Meetings

Monday Oct 3		Tuesday Oct 4		Wednesday Oct 5		Thursday Oct 6		Friday Oct 7		Saturday Oct 8		Sunday Oct 9	
9-12	14-17	9-12	14-17	9-12	14-17	9-12	14-17	9-12	14-17	9-12	14-17	9-12	14-17
				SC 62A JWG 7 Inter City Room 10	SC 62A JWG 7 Inter City Room 10	SC 62A JWG 7 Inter City Room 10	SC 62A JWG 7 Inter City Room 10	SC 62A JWG 7 Inter City Room 10	SC 62A JWG 7 Inter City Room 10				SC 62A CAG Inter City Room 10
SC 62A JWG 7 62304 VDE Siemens	SC 62A JWG 7 62304 VDE Siemens	SC 62A JWG 7 62304 VDE Siemens	SC 62A JWG 7 62304 VDE Siemens	SC 62A JWG 7 62304 VDE Siemens		SC 62A MT 23 Inter City Room 9	SC 62A MT 23 Inter City Room 9	SC 62A MT 23 VDE Hertz	SC 62A MT 23 VDE Hertz	SC 62D WG 33 VDE Hertz	SC 62D WG 33 VDE Hertz		SC 62B CAG Inter City Room 8
		SC 62B MT 51 Maritim Saal 1	SC 62B MT 51 Maritim Saal 1	SC 62B MT 51 Maritim Saal 1	SC 62B MT 51 Maritim Saal 1	SC 62B MT 51 Maritim Saal 1	SC 62B MT 51 Maritim Saal 1	SC 62D JWG 3 VDE Braun	SC 62D JWG 3 VDE Braun	SC 62D JWG 3 VDE Braun	SC 62D JWG 3 VDE Braun	SC 62D MT 19 VDE Reis	SC 62D MT 19 VDE Reis
				SC 62B MT 32 VDE Lichten- berg	SC 62B MT 32 VDE Lichten- berg	SC 62B MT 32 VDE Lichten- berg	SC 62B MT 32 VDE Lichten- berg	SC 62B MT 32 VDE Lichten- berg	SC 62B MT 32 VDE Lichten- berg	SC 62C WG 1 Inter City Room 9	SC 62C WG 1 Inter City Room 9	SC 62C WG 1 Inter City Room 9	SC 62C WG 1 Inter City Room 9
	SyC AAL Plenary Maritim Saal 1+2			SC 62A JWG 1 Inter City Room 8	SC 62A JWG 1 Inter City Room 8	SC 62A JWG 1 Inter City Room 8	SC 62A JWG 1 Inter City Room 8	SC 62A JWG 1 Inter City Room 8	SC 62A JWG 1 Inter City Room 8				SC 62D CAG Inter City Room 10
Monday Oct 10		Tuesday Oct 11		Wednesday Oct 12		Thursday Oct 13		Friday Oct 14					
9-12	14-17	9-12	14-17	9-12	14-17	9-12	14-17	9-12	14-17				
SC 62A Plenary Steigen- berger Room 6	SC 62A Plenary Steigen- berger Room 6	SC 62B Plenary Con-gress Center Harmony Hall D1	SC 62C Plenary Con-gress Center Harmony Hall D1	SC 62D Plenary Maritim Saal 3	TC 62 CAG Maritim Saal 3	TC 62 CAG KAP-C1	TC 62 Plenary KAP-C1- Satellit						
SC 62C WG 1 Con-gress Center	SC 62C WG 1 Con-gress Center												
SC 62D MT 19 VDE Reis	SC 62D MT 19 VDE Reis												
Evening Opening Ceremony Festhalle Frankfurt				Evening Fare-well Party for Rudy Godinez Congress Center				Evening Farewell Party Palmengarten Frankfurt					

Monday Oct 17		Tuesday Oct 18		Wednesday Oct 19	
9-12	14-17	9-12	14-17	9-12	14-17
SC 62A PT 62354 VDE Siemens	SC 62A PT 62354 VDE Siemens	SC 62A WG 14 VDE Siemens	SC 62A WG 14 VDE Siemens	SC 62A WG 14 VDE Siemens	SC 62A WG 14 VDE Siemens





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VLADIVOSTOK 2017

Forthcoming Meetings

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ
И ТОРГОВЛИ РОССИЙСКОЙ ФЕДЕРАЦИИ
**ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО
ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ
И МЕТРОЛОГИИ**
(Росстандарт)



MINISTRY OF INDUSTRY AND
TRADE OF RUSSIAN FEDERATION

**FEDERAL AGENCY
ON TECHNICAL REGULATING
AND METROLOGY**
(Rosstandart)

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Leninsky prospekt, 9, Moscow, Russia,
V-49, GSP-1, 119991

Fax: +7 (499) 237-98-15

02.06.2016 № 67-7972/01

To: Mr. Michael Appel, IEC/TC 62 Chairman
Mr. Norbert Bischof, IEC/TC 62, IEC/SC B and IEC/SC 62C Secretary
Mr. Justin P McCarthy, IEC/SC 62A Chairman
Mr. Charles Sidebottom P.E., IEC/SC 62A Secretary
Mr. Yan Kang, IEC/SC 62B Chairman
Mr. Geoffrey S. Ibbott, IEC/SC 62C Chairman
Mr. Jürgen Stettin, IEC/SC 62D Chairman
Mr. Jeffrey L. Eggleston, IEC/SC 62D Secretary

Dear Sirs,

The Russian National Committee for the IEC (Federal Agency on Technical Regulating and Metrology) invites the IEC/TC 62 "Electrical equipment in medical practice", IEC/SC 62A "Common aspects of electrical equipment used in medical practice", IEC/SC 62B "Diagnostic imaging equipment", IEC/SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", IEC/SC 62D "Electromedical equipment" and their WGs to carry out the Plenary meeting and the meetings of SCs and WGs in the framework of the 81st IEC General Meeting on 2^d-13th October 2017 in Vladivostok (Russian Federation).

In case of acceptance of our invitation, we would be very grateful to you if you let us know of the desired dates for the meeting(s) and estimated number of delegates.

For organizing of the 81st IEC GM the Russian NC will found the Organizing Committee. It will be responsible for all questions, concerning the meetings, such as sending invitations, hotel reservations, holding of working meetings and cultural events.

With best regards,

Mr. Boris Potemkin
Deputy Head of the Federal Agency on Technical Regulating and Metrology

c: Mr. Laurent Maily, IEC Technical Officer

From: IEC TC 62 (Norbert Bischof/Annette Hagen) Sent: Mi 08.06.2016 09:36
To: npankratova@gost.ru
Cc: lma@iec.ch; Michael.Appel@nghs.com; justin@dineng.co.uk;
 chuck@pstandards.com; kangyan@bmie.neu.edu.cn;
 ACohen@accuray.com; juergen.stettin@haw-hamburg.de;
 Jeffrey.Eggleston@medtronic.com; 'CHOE, Hae (hchoe@aami.org)';
Subject: RE: 81st IEC General Meeting 2017 - Invitation

Dear Ms. Pankratova,

The invitation of the Russian NC is highly appreciated. I would like to thank you also on behalf of the TC 62 Chair Mr. Appel, and the TC 62 Secretary Mr. Bischof.

We are glad to accept the invitation. Desired dates for TC, SC, WG meetings and estimated number of delegates will follow soon.

With kind regards,

Annette Hagen
Assistant Secretary IEC TC 62, IEC SC 62B, IEC SC 62C
E-mail iectc62@cocir.org





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THANK YOU!

Norbert Bischof,

Secretary IEC TC 62, SC 62B and SC 62C

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Nicole Denjoy

DITTA Vice-Chair & COCIR Secretary General

denjoy@globalditta.org