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| **Reported by (Name):** | **Geoffrey S. Ibbott, Ph.D.** |
| **Organization:** | **International Electrotechnical Commission** |
| **Position Title:** | **Chair, US TAG; Technical Advisor to US National Committee; Convenor, 62C Working Group 1** |
| **Activity:** | **Meeting of IEC Working Group 1 of Subcommittee 62 C** |
| **Meeting Dates:** | **Mar 25-29 2019** |
| **Meeting Location:** | **Frankfurt, Germany** |
| **Payment $:** | **Travel supported by ASTRO** |
| **Reasons for Attending or not Attending** | **Attended as convenor of WG 1** |
| **Issues from Previous Meetings or Year:** | **Ongoing…** |
| **General Description of Activities of the Organization and/or Meeting:** | **Continue progress on development of new and updated IEC standards. Additional opportunity to meet with German standards committee to discuss collaboration and future joint meetings** |
| **Issues for AAPM:** | **None** |
| **Budget Request ($):** | **Included in WG IEC budget** |

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**INTERNATIONAL ELECTROTECHNICAL COMMISSION**

**Report of Meeting of Working Group 1**

**March 25th to 29th 2019 in Frankfurt, Germany**

**Meeting venue:**

German National Committee (DKE)

Schreyerstrasse 4-6

60596 Frankfurt

GERMANY

**Begin**: 2019-03-25, 09.00

**End:** 2019-03-29, 17.00

***Opening of Meeting***

The Convenor opened the meeting at 09.00 on 25 Mar 2019 and thanked DKE (the German Commission for Electrical, Electronic and Information Technologies) for providing the meeting space and for providing lunch each day. He also, at a later moment, thanked the Japanese members for providing Japanese cookies for the coffee breaks. As explanation for those unfamiliar with the German standards structure, DKE is a joint organization of the German Standards Institute (DIN) and the VDE, a technical-scientific association focused on electrical, electronic and information technology. The DKE is the German member of European organizations such as CENELEC and is the German national member of the IEC.

***Attendance***

The following members participated on one or more of the meeting days:

John Allen (UK)

Norbert Bischof, Secretariat (Germany)

Caterina Brusasco (Belgium)

Alan Cohen, Subcommittee chair (USA)

Stefan Danuser (Switzerland)

Akifumi Fukumura (Japan)

Wilhelm Goldstein (Germany)

Jürgen Heese (Germany)

Paco Hernandez-Guerra (USA)

HsinLu Hsu (USA)

Geoffrey Ibbott, WG Convenor (USA)

Thomas Jakob (Switzerland)

Kari Jyrkkälä (Finland)

Per Kjäll (Sweden)

Dominik Kowalski (Germany)

Anna Olsson (Sweden)

Werner Reichel (Germany)

Abdul Sayeed (UK)

Hans Sethi (UK)

Frederic Stichelbaut (Belgium)

Kazuo (“Elvis”) Tomida (Japan)

The Convenor reviewed the IEC Code of Conduct, and then the group reviewed the agenda and the structure of the meeting days.

***Reports***  
The group received reports from the Convenor, Chair, and Secretariat. The Convenor reviewed the work program of the WG and the agenda. The agenda was approved.

***Introduction of German National Standards***

Mr. Bischof introduced Dr. Klaus Neuder, Mr. Johannes Dehm, and Prof. Dr. Gunther Gademann, MD PhD. Dr. Neuder is head of the Health section of the DKE. Mr. Dehm is Managing Director of the Normen-Ausschuss-Radiologie (NAR, or “Standards Committee for Radiology”) which is affiliated with the DIN. Prof. Gademann is Chair of the German “mirror committee” AA5 on Radiotherapy of the NAR. The NAR is composed of members drawn in equal numbers from industry, the clinic, and regulatory authorities, and functions as a technical advisory group to the DIN.

AA5 interfaces with CEN, ISO TC 85 SC 2, CENELEC TC 62 and IEC SC 62C. AA5 has translated several of the most significant IEC standards into German for application in Germany but has prepared a number of their own standards for which there is no exact IEC counterpart, including standards for radiotherapy treatment planning systems, stereotactic radiosurgery, and IMRT, among others.

Recent changes due to adoption of the Medical Device Regulations in Europe (replacing the Medical Device Directive of 2013) have dictated that standards for medical devices in Germany be taken from international standards, rather than German national standards. Prof. Gademann indicated that there could be benefits for both the German standards organizations and the IEC by collaborating. The existing German standards contain well-reasoned provisions that could contribute to revisions of IEC standards, or development of new IEC standards. At the same time, the adoption of IEC standards in Germany would enhance the status and influence of the standards in Germany and presumably elsewhere in Europe.

Prof. Gademann described several DIN standards (6873-1 and 6873-5) on radiotherapy treatment planning systems and another (6827-1) on the recording of treatments from external beam equipment. He suggested that the provisions of the DIN standards be considered as WG 1 is presently undertaking to update and prepare new editions of both the treatment planning safety standard (IEC 62083) and the treatment management system standard (IEC 62274).

WG 1 members indicated their interest in investigating a collaboration and agreed to focus initially on preparing a translation of DIN 6873-1 as WG 1 is well along in preparing a new edition of IEC 62083. Prof Gademann committed to preparing an English translation within a month and delivering this to WG 1 for review and consideration of a meeting to determine the opportunities for incorporating provisions of DIN 6873-1 into IEC 62083.

A subsequent project will be to perform a similar analysis of DIN 6827-1 and its relevance to IEC 62274.

Prof. Gademann also extended an invitation to WG 1 to consider holding an upcoming meeting in conjunction with a meeting of AA5, to be held in late March 2020 in Berlin. G. Ibbott agreed that WG 1 would consider this.

***Swedish proposal for security of sources:***

Per Kjäll from the Swedish national committee attended to present this proposal. He had presented an earlier version several years ago but has since refined the approach. He explained that the risk of theft of sources and their use in terrorism is real. Several Nuclear Security Summit meetings, most recently in 2016, have said that this threat is one of the world’s greatest challenges and countries must address it. The IAEA and NCRP have published recommendations. But implementation is ambiguous and insufficient. Regulations generally are written for security, not safety. IAEA and IRPA have recommended integration of safety and security, but this has not been adopted widely. As a result, countries provide different ad hoc solutions which are inefficient. Kjäll believes an international standard is needed to fill the gap.

Some of the issues are that safety aspects often are not considered, such as patient/staff safety, equipment operability, serviceability and maintainability.

Kjäll and colleagues will revise the NWIP, especially the Scope, to keep narrow enough to propose within 62C. He will consider including the facility (vault) in the scope, as 62B has done for MRI.

We will also forward to ISO TC 85 for their consideration.

***Status of TC 62:***

Norbert Bischof reviewed the scope and structure of TC 62. The second amendment of 60601-1 expected to be published in mid-2020. We should expect changes to affect our -2 standards. A 4th edition of 60601-1 is expected in the 2024 – 2026 time frame.

***IEC 60601-2-64, Light ion safety: Japanese proposal for an amendment***

Kazuo “Elvis” Tomida presented a proposal that has been developed by himself, Caterina Brusasco, Michael Moyers and others. We will circulate a DC to NCs and combine a Q document into the DC. If there are no objections and a majority of NCs approve the project to amend, we can assume consensus.

The amendment will include harmonisation with the 62667 performance standard, including terms and definitions, and editorial corrections. It will also include harmonisation with the linac standard, especially the issue of integration of external systems.

Finally, the amendment is expected to address out-of-field dose issues.

***IEC 61217, Coordinates***

Geoff Ibbott reviewed the status of the draft and comments received from the Belgian and Swedish members of the WG.

Agreed that the next steps will follow this timeline:

During April – June – Geoff to incorporate comments received into a draft CD.

July 12, 2019 – Submit review report (RR document) to Central Office, stating that CD will be delivered, and the project registered within one week

July 19, 2019 – Deliver first CD of a 3rd edition of 61217 to Central Office

Sept 20, 2019 – Deadline for receipt of NC comments

Oct 20, 2019 – Review of NC comments at WG 1 meeting (Shanghai)

***IEC 60601-2-1 E4: Review of WG member comments on pre-FDIS draft***

Alan Cohen led the group through the comments that had been received from WG members and from CO. For neutron leakage, the standard now clarifies that the manufacturer must measure and report the value in the accompanying documents. For dose delivered during beam hold, we removed one requirement and clarified others to make clear that beam hold dose rate must be <0.1% of reference dose rate, and that dose delivered during beam hold must be < 0.025Gy in a treatment session or beam must terminate.

Our goal is to prepare an FDIS for distribution within the next few months and distribute to NCs so that comments and votes can be received in advance of the October meeting.

***IEC TR 63183, Error messages:***

Alan Cohen reviewed edits he had made in response to comments on 62C/713/CD and comments that were submitted early on 62C/738/DTR.

Most of the comments that were sent to the WG were accepted. Alan will complete changes to the DTR. If any significant comments are received following the comment deadline (Friday) Alan will alert the WG and possibly schedule a WebEx to discuss. Otherwise, he will distribute the edited text for final review before submitting to the Secretariat for forwarding to CO.

***IEC 60601-2-68/A1, IGRT***

Thomas Jakob led a discussion of changes needed urgently, based on discussion of IEC 62083. He had prepared an early draft of 60601-2-68 with tracked changes that he proposed were needed. The WG reviewed each of the changes. Extensive discussion was held on the question of requirements to be applied when the equipment is operating in normal condition as opposed to single-fault condition. Another topic that required discussion was the question of the coordinate system of independent imaging equipment and how it should be related to the accelerator coordinate system. This question will need to be addressed in the revision of 61217 also. Further discussion was held on the storage and display of image data, for off-line, on-line and real-time IGRT. The handling of this issue is complicated by the realization that IGRT systems are generally integrated with other equipment (e.g., R&V, OIS, treatment unit) and the integration can be handled differently from one system to another.

***Discussion of an X-IGRT performance standard***

Thomas Jakob had prepared a very early draft NWIP for a performance standard that could be distributed to National Committees with a questionnaire asking for support. The draft was largely based on IEC 60976 for linear accelerator performance. Discussion was held over the problems the linac performance documents have created in some countries that have interpreted them as safety standards and have required testing to determine compliance. It was agreed that a performance standard would only include recommended performance levels where it was felt to be essential for performance. It was pointed out that Thomas was already very busy between the amendment to the X-IGRT safety standard and a new edition of the treatment planning safety standard. He recommended Dominik Kowalski as project leader for the X-IGRT performance standard. This was endorsed by the WG.

***Safety standards for MR-IGRT, optical surface guided RT, etc.***

Discussion centered around the best way to address safety of non-x-ray IGRT systems. One thought was that other imaging systems might be incorporated into the existing safety standard. It was proposed that John Allen begin by considering performance and safety expectations for MR-IGRT. It was also proposed that we contact a representative of one or more of the optical surface-guided systems to begin considering requirements for SGRT systems. It might be valuable for the putative project leaders to meet to discuss commonalities and differences, to determine if one or multiple standards are most appropriate. Dominik Kowalski volunteered that his company is marketing an optical surface-guided system.

***IEC 62083, Treatment planning safety.***

Thomas Jakob lead a discussion on comments received on 62C/735/CD. National Committees had submitted numerous comments (most from the US, Sweden and Switzerland) with the result that approximately 400 comments needed to be reviewed. Extensive discussion was held on a number of topics including requirements for manufacturers to define the hardware and certain software (operating system, virus protection) that has been validated for the treatment planning software, as well as updates.

Due to the large number of comments received it was agreed that a second CD should be distributed before we move on to a CDV. Further work will be needed, especially on requirements for planning systems for brachytherapy, and this will be scheduled for an upcoming meeting.

***IEC 62274, R&V Systems:***

Thomas Jakob lead a discussion of changes needed urgently and thoughts regarding a new edition. Thomas reviewed a proposal for a new edition of the standard which will be broadened to address all devices that can be called Treatment Management Systems (TMSs). Agreed that we will learn a lot as we finish the TPS standard and the linac safety 4th edition. A lot of provisions have been moved to the RTPS and EBE standards, but scheduling is a necessary focus. Some topics, such as plan approval, might be handled by the RTPS or the TMS and so both standards will need to address this. Dose tracking and dose accumulation should be included. This standard needs to reflect how a TMS works in the real-time environment.

***Discussion of RT clauses of IEC 60601-2-44***

Werner Reichel reported that 62B plans to remove clause 201.101 “Requirements for CT scanners providing images for radiotherapy treatment planning.” If they are successful, it will affect a number of issues for Radiotherapy. One issue is the use of lasers for patient alignment and their connection to the CT scanner. At the moment, no one seems to be responsible for the accuracy and connections of the lasers. Another is specifications regarding the allowable deviation from horizontal of the patient support, and from vertical (or the stated tilt angle) of the gantry.

Our concerns can be grouped into three topics:

1. What should be written into this chapter to ensure we get useful data for treatment planning.
2. 60601-2-44 should align with clauses in 60601-2-68 that ensure safety when we have a CT scanner in the RT bunker.
3. Some RT devices (Halcyon, United Imaging) seem to be included in the definition of CT scanner, so might be required to comply with all provisions of 60601-2-44.

Werner told the Convenor of the MT 30 that he thought the two convenors should communicate. But the MT Convenor is from GE and may be focused more on the manufacturer’s perspective, so Geoff needs to reach out. Werner is a guest of the German mirror committee for the CT standard, and has an avenue of input. However, he is aware that the mirror committee is interested in the production of high-quality images but is not interested in how the images are used once they are produced.

We went through the existing Clause 201.101 and proposed edits. The Convenor thanked Werner for making the proposal.

***Discussion of future projects and priorities***

Although lower priority than the topics above, it is recognized that we need to prepare new editions of IEC 60976 and IEC TR 60977. John Allen agreed to do some preliminary work. This will next be discussed at the WG-1 meeting in October.

***Future Meetings***

A meeting of the project team on 62083 is proposed for June 2019 in Stockholm, with the emphasis on incorporating brachytherapy requirements. A meeting of the project team on the IGRT standard is proposed for August 2019 in Munich.

The next plenary meeting of WG 1 will be held in conjunction with the IEC General Meeting scheduled in Shanghai from October 20 to 23, 2019.

Respectfully submitted,

Geoffrey Ibbott

Convenor IEC 62 C/WG 1