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| **Reported by (Name):** | **Geoffrey S. Ibbott, Ph.D.** |
| **Organization:** | **International Electrotechnical Commission** |
| **Position Title:** | **Convenor, Working Group 1; Chairman, Subcommittee 62C** |
| **Activity:** | **Annual meeting of Technical Committee 62, its subcommittees and Working Groups** |
| **Meeting Dates:** | **October 12-14, 2010** |
| **Meeting Location:** | **Seattle, WA** |
| **Payment $:** | **Travel reimbursement** |
| **Reasons for Attending or not Attending** | **Attended to chair WG 1 and 62 C meetings, and to represent US medical physics community** |
| **Issues from Previous Meetings or Year:** | **See report** |
| **General Description of Activities of the Organization and/or Meeting:** | **See report** |
| **Issues for AAPM:** | **See report** |
| **Budget Request ($):** | **See budget request** |

**Report of Meeting: International Electrotechnical Commission**

The AAPM participates in the development of international standards and technical reports for the safety and performance of electrical equipment, specifically, equipment related to the delivery of radiation therapy. This is accomplished though a group called the U.S. Technical Advisory Group (U.S. TAG) consisting of representatives from ASTRO, ACR and AAPM as well as those in industry. This group advises the U.S. National Committee (USNC) of the International Electrotechnical Commission (IEC), a Committee of the American National Standards Institute. Since 1993, Geoffrey Ibbott, Ph.D has been USNC Technical Advisor, chair of the U.S. TAG, and a liaison between the U.S. TAG and the USNC. Since 2006, he has been chair of subcommittee 62C.

The IEC develops standards for the design of electrical equipment, and medical electrical equipment specifically is handled by its subcommittee 62C. Working Group 1 of 62C deals with equipment used for radiation therapy. These standards have immediate and far-reaching consequences on the design and operation of radiation therapy equipment. For example, the Working Group has published standards that set acceptable levels of leakage radiation, requirements for dosimetric safety and accuracy, and standards for parameters such as gantry angle conventions.

Dr. Ibbott represents the US radiation oncology community at meetings of IEC Working Group 1, Subcommittee 62C and Technical Committee 62. The membership of these committees is at least 50% manufacturers’ representatives, so maintaining a clinical medical physics presence is critical.

A meeting of the IEC (a “general meeting”) was held October 4-16, 2010 in Seattle, Washington. This involved meetings of 90 Technical Committees and Subcommittees, and numerous Working Groups. Approximately 2,800 delegates were in attendance. The meeting was planned and organized by the US National Committee through its headquarters at the American National Standards Institute. Of interest to the AAPM were the meetings of Technical Committee 62 and its Subcommittees. This report addresses meetings of TC 62, SC 62C and WG-1.

Working Group 1 met October 12-14, although a subgroup met October 10-11. This was one of the best attended WG-1 meetings, with 22 representatives from ten countries in attendance. Countries represented included the USA, Canada, Brazil, the UK, Germany, Sweden, Switzerland, Belgium, Japan, and China. However, as is often the case, the majority of attendees were representatives from industry.

The agenda and discussion was as follows:

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| **1** | Welcome – Opening remarks – Finalize Agenda |
|  | Discussion to rearrange agenda to accommodate the availability of some of the members. Agreed. |
| **2** | Election of the Chairman for the meeting |
|  | Ibbott elected chairman, will ask Willi Goldstein to chair on Wednesday. |
| **3** | Short presentation on the administrative details of the IEC general meeting |
|  | This was not held. Mr. Baillif was not available. |
| **4** | Proposals for a new Convenor |
|  | Ibbott to be proposed. Bernd to submit formal proposal for distribution to NCs.  Also approved Michael Moyers to continue as project leader for the light ion standards. |
| **5** | Ion therapy. To receive report from WP on progress to CDs. |
|  | Moyers reported on the meetings of the WP held in March in Brussels, in May in Japan, and in Seattle immediately prior to the WG-1 meeting.  WP wants one more face2face meeting before distributing CD for -2-64.  WP has not made as much progress on performance standard, and will use web-conferences to make further progress.  Wanted discussion about how to incorporate IGRT requirements: Either refer to a separate IGRT standard, amend linac standard for IGRT requirements, or incorporate clauses directly?  Hans proposes to hold discussion after review of IGRT standard on Thursday. However, too many people on the light ion WP won’t be here.  Further discussion was held. Willi pointed out that safety should not depend on the type of equipment. He thinks there should be a single standard for IGRT. |
| **6** | IEC 60601-2-8, Safety of x-ray therapy systems. To note progress of FDIS, 62C/499/FDIS. |
|  | Inger-Lena led the discussion on the comments received. Most comments were editorial. Also included a reference that 60601-1-9 applies. Votes to be received by 10/15/2010; if successful, will go on to publication. |
| **7** | IEC 60601-2-1, Safety of radiation therapy linear accelerators. To discuss Amendment 1 following the negative assessment from Richard Mellish. |
|  | Discussion about the relationship to the NYC accidents. Agreed that it was appropriate for the IEC to look closely at its documents to assure that any appropriate changes are made. Also discussed whether the proposed changes are appropriate for 60601-2-1 or for the R&V safety standard. Agreed that we will only amend -2-1 for now. Agreed that Claus and Gaby will work together to develop wording to be used for the proposed changes to 201.10.1.2.101.1.5 (see A1 draft.) Hans will contact Richard Mellish to discuss his concerns. Then Hans will prepare a new draft A1 in early November. This will be circulated by Bernd as a CDV as soon as practical. |
| **8** | IEC 60601-2-11. To discuss NC comments on CDV, 62C/494/CDV. |
|  | Willi reviewed the comments, including many from Richard Mellish. The WG-1 was able to complete discussion on only the truly technical comments. Proposed that Willi will prepare a complete response to the comments and hope for a F2F meeting with Richard Mellish. He, Hans, and Inger-Lena will try to arrange this. At the next meeting, Willi hopes to present proposed changes that have the agreement of the working party as well as Richard Mellish.  A change was made to reference 60601-1-9 (Environment).  Willi and the WP responded to other technical comments. The WG-1 agreed that the changes were not so significant to require another CDV, so after the next WG-1 meeting, Willi will prepare a FDIS. |
| **9** | IEC 60601-2-17, Safety of remote afterloaders. To discuss NC comments on CDV, 62C/492/CDV. |
|  | The national committee comments were reviewed and many complex issues were discussed in detail. Ibbott will prepare a WG draft containing the changes for discussion at the next WG-1 meeting, before proceeding to an FDIS.  A change might be needed to reference 60601-1-9 in 201.1.3 of -2-17. Ibbott to include a statement that 60601-1-9 does apply. |
| **10** | IEC 61217. To discuss NC comments on CDV, 62C/493/CDV. |
|  | The NC comments were discussed. Claus will make the necessary changes and will prepare an FDIS. He will do this before Christmas, then Bernd will send for French translation. It will then go for review and presumably publication. |
| **11** | DICOM conformance - equipment connectivity. To receive any progress report from Hans on ASTRO/DICOM working party |
|  | Hans presented a report from DICOM WG-7. The WG is addressing new requirements for workflow management for radiotherapy delivery. They are also looking at development of second-generation RT objects to address new technologies in RT such as adaptive RT. Hans will try to get drafts for review. Claus and Michael reported on the ion beam subgroup of WG-7. Their effort is concerned presently with the amount of data that needs to be transmitted. They are also discussing technologies that haven’t been implemented widely, and whether or not the standard should try to address them. |
| **12** | IEC 60601-2-X (IGRT). To note progress of NWP, 62C/498/NP |
|  | The proposal is for a new part 2 standard that will address image-guidance systems. Much discussion was held over whether this should be a part 2 standard. Agreed it should, because it satisfies the definition of me equipment. Next was discussion on whether this should be a 62B standard as it deals with imaging. It clearly should not, as the requirements for image guidance are very different than those for diagnosis. Another discussion was held over whether to include types of IGRT systems other than x-ray imaging, such as PET and MR. No, we decided to limit it to x-ray imaging systems. Also, a discussion was held over whether this standard should address IGRT with treatment units other than linear accelerators. It was agreed that light ion accelerators should be included. Next, we discussed how to define IGRT. Should we include “adaptive RT”? No, it was agreed we would not.  NCs must submit comments by 10/29. We must also nominate an expert. |
| **13** | IEC 60601-2-44. To receive a progress report on collaboration with 62B MT30. |
|  | There has been no report from the MT. A meeting was held in September. Inger-Lena was asked to review the document. She asked that the CD be sent out as a joint B/C document, as was the case with the NWP. Question about why -44 says 60601-1-9 does not apply. Also concerns about the way -44 describes a CT scanner as containing x-ray source and detectors in a single cover, toroidal shaped. Graham and Stephen questioned the definition – doesn’t seem to exclude Tomo unit. Comments on amendment were due 9/3/2010. A CDV is likely to appear next year. |
| **14** | Future work and tasks. |
|  | Hans discussed an amendment to the 3rd edition of the General Standard: The amendment has been distributed, and Hans displayed several pages of unresolved NC comments in response to the amendment. The comments from 7940 to 8770 all address clause 10.1 and require our attention. Geoff should send formal response from 62C to Chuck Sidebottom. Timeframe is by end of October. Graham and Steven, Gaby Suft volunteered. Geoff recruit one or two more from US TAG.  Proposal for new collateral standard from 62A regarding emergency environment. WG-1 must respond by end of October: does this proposed collateral standard influence our -2 standards.  Hans described an amendment 1 to 3rd edition of -1. Clause 18 was added to address “Medical software system”. There was opposition to including it in -1, and it has been withdrawn. A recommendation was passed by 62A (to take to TC 62 on Saturday) that a new product standard be developed for standalone software led by SC 62A. (IEC 62304 will remain a software life cycle standard.) It was noted that a new standard might overlap or conflict with clause 14 of the general standard, which was written to replace collateral standard 60601-1-4.  Hans also described a report addressing the structure of the IEC. He noted that the current structure was developed when most ME equipment was hardware, but it is now largely and sometimes exclusively software. IEC structure doesn’t reflect structure of other organizations that exist in our area. Yesterday, 62 CAG discussed and considered whether changes to TC62 structure are needed. Sidebottom presented a paper discussing options. Agreed that Joint Working Group 7 (with ISO/IEC – it deals with risk management for IT) to address this.  At same time, changing the scope of TC62 to include health information security and confidentiality, the loss of which can reduce safety. Another group has been established to look into this (but we’re having trouble seeing why the IEC needs to jump into this.) |
| **15** | Date and place of next meeting. |
|  | Date: Spring, 2011  Venue: Stockholm  Proposed Agenda:   * 60601-2-1 draft amendment * 60601-2-11 draft of CDV * 60601-2-17 draft of CDV * IGRT committee draft * Light ion committee draft * Discussion about icons and IEC 80416-1, IEC 60878 * Discussion about 60601-2-44 and relationship to IGRT |