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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, Chairman US TAG** |
| **Activity:** | **Semi-annual meeting of US TAG** |
| **Meeting Dates:** | **March 6, 2013** |
| **Meeting Location:** | **Rosslyn, VA** |
| **Payment $:** | **Hotel reimbursement** |
| **Reasons for Attending or not Attending** | **Attended to chair meeting of US TAG to develop consensus position of the US medical physics community** |
| **Issues from Previous Meetings or Year:** | **See report** |
| **General Description of Activities of the Organization and/or Meeting:** | **See report** |
| **Issues for AAPM:** | **See report** |
| **Budget Request ($):** | **See budget request** |

**Meeting Report**

**IEC Subcommittee 62C, Working Group 1**

**Rosslyn, Virginia**

**March 6, 2013**

**Introduction**

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 IEC subcommittee 62C. In 2011, Dr. Ibbott was elected Convenor of Working Group 1.

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.

The agenda and a brief report of the meeting are below. Several important items were discussed and will be reported on in the near future.

**Meeting Report**

The US TAG met on March 6, 2013, to work on the light-ion standards. The meeting was attended in person by Moyers, Cohen, Biggs, West, Galvin, Fitzer and Ibbott. Purwar, Lukey, Coon and Solodkin attended by conference call.

The agenda consisted of preparation of comments for submission by the US National Committee to the CDV of 60601-2-64.

The US TAG spent the day going through the draft standard. Numerous edits had been prepared in advance by Moyers, who is one of the principal authors of this standard. The US TAG recommended a large number of editorial comments and a significant number of substantive technical comments. The complete report is attached below.

Respectfully submitted,

Geoffrey Ibbott, Convenor, WG 1; Chair, Subcommittee 62C; and Chair, US TAG

Annex

| Date | Document | Project Nr. |
| --- | --- | --- |
| 02.03.2013 | 62C/554e/CDV | IEC 60601-2-64 |

| National Committee | Line number | Clause/ Subclause | Paragraph Figure/ Table | Type  of comment (General/ Technical/Editorial) | COMMENTS | Proposed change |
| --- | --- | --- | --- | --- | --- | --- |
| US1 | 107 | Introduction |  | T | The 3rd paragraph appears to give the customer the ability to “opt out” of site tests. Site tests are written to assure safety and essential performance, and should not be optional for the manufacturer. | Revise the 3rd sentence to read:   1. It is understood that SITE TESTS shall be performed but may or may not be performed by the MANUFACTURER, per the agreement between the MANUFACTURER and end user. |
| US2 | 130 | 201.1.1 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US3 | 8 places |  |  | E | Font of "Note" is inconsistent | always use "Note" |
| US4 | 166 | 201.1.2 |  | E | Correct the grammar | Add “to” before “specify tests” |
| US5 | 191 | 201.1.3 |  | E | List collateral standards in numerical order | Move 60601-1-3 to the top of the list. |
| US6 | 272 | 201.3 |  | E | Inconsistent references | Add "IEC" in front of second reference |
| US7 | 305 | 201.3.207 |  | E | Correct the grammar | Add “and” before “with additional information”. |
| US8 | 349 | 201.3.217 |  | E | Add abbreviation | Add “(LSD)” to end of line. |
| US9 | 359 | 201.3.218 |  | E | Correct the grammar. | Remove “is” from before “specified”. |
| US10 | 380-381 | 201.3.222 |  | E | Correct typo.  Some systems may monitor energy instead of range. This sentence should be consistent with rest of document. | Revise as: “ACCESSORIES”.  change "of the range monitoring system" to "of the energy or range monitoring system." |
| US11 | 409 | 201.3.228 |  | E | “Portal” is defined term | change to portal |
| US12 | 439 | 201.3.233 |  | E | Correct the grammar. | Revise as: “…uniform scanning and modulated scanning.” |
| US13 | 446 | 201.3.235 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US14 | 451 | 201.3.236 |  | E | Clarify the definition | Add to end of sentence “and upon which the patient is placed.” |
| US15 | 470 | 201.3.237 |  | E | End sentence with period | Add period |
| US16 | 565 | 201.7.4.101 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US17 | 762 | 201.9.2.101 |  | T | Delete “7),” because a test is not required.  Format of compliance statement is incomplete | Revise:  Type test grade B – 3), 4), and 8) - Verify by inspection and measurement that the limits are not exceeded. |
| US18 | 767 | 201.9.2.101 |  | T | Separate into two lines for subclauses b) and c) and revise. | Revise:  b) type test grade B – 1) Verify by inspection and measurement that the limits are not exceeded.  c) type test grade B – 1) Verify by inspection and measurement that the limits are not exceeded. |
| US19 | 769 | 201.9.2.101 |  | T | Separate into three lines, for subclauses a), b) and c) | Revise:   1. type test grade B – 5) Verification… 2. type test grade B – 2) , 3) Verification… 3. type test grade B – 2) , 3) Verification… |
| US20 | 798 | 201.9.2.102 |  | E | Correct grammar | Revise: “…parts can not be operated…” |
| US21 | 812 | 201.9.2.102 |  | E | The word "that" is missing | add the word "that" after “review” |
| US22 | 866 | 201.9.2.104 |  | T | Revise bullet b) for consistency with the IGRT standard. | Revise:  b) The equipment must require an action at the TCP at the time a connection is established and before any functions or movements are controlled remotely; |
| US23 | 884 | 201.9.2.104 |  | E | Revise to clarify temporal nature of requirement. | Revise: “…remote site without first providing…” |
| US24 | 922 | 201.9.8.101 |  | E | Incorrect font | Correct “*functions*” |
| US25 | 935 | 201.9.101 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US26 | 942 | 201.9.101 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US27 | 963 | 201.10.2.2.101.1 |  | E | Delete hyphen | Delete hyphen |
| US28 | 963 | 201.10.2.2.101.1 |  | E | Clarify | Insert “light ion beam” before “irradiation”. |
| US29 | 973 | 201.10.2.2.101.1 |  | E | Incorrect word. | Replace “devices” with “device”. |
| US30 | 977 | 201.10.2.2.101.1 | b) | T | Revise the grammar | 1. Revise as: 2. *Type test grade A – Verify that the accompanying documents describe the means …”.* |
| US31 | 980 | 201.10.2.2.101.1 | c) | T | Revise the grammar | 1. *Revise as:* 2. *Site test grade B – Principle: Verify correct functioning of displays for all possible selections.* |
| US32 | 1003 | 201.10.2.2.101.2 | b) | E | Revise for clarity. | 1. Revise as: 2. *type TEST grade B – Verify that the LIGHT ION species is displayed before and during IRRADIATION.* |
| US33 | 1006 | 201.10.2.2.101.2 | b) | T | Wording for site test should be consistent with type test. | 1. Revise as: 2. *site TEST grade B – Verify that the LIGHT ION species is displayed before and during IRRADIATION.* |
| US34 | 1008 | 201.10.2.2.101.2 | c) | E | Revise test for clarity and consistency with IEC format. | Revise:  *Type test grade A – Compliance is checked by inspection of the risk management file.* |
| US35 | 1011 | 201.10.2.2.101.2 | c) | T | Revise test for clarity | *Site test grade C – Demonstrate that the means described in the risk management file are correctly implemented.* |
| US36 | 1024 | 201.10.2.2.101.3 | Note | E | Redundant use of “bending magnet”. | Delete the term "bending magnet" immediately before "magnetic field” |
| US37 | 1025 | 201.10.2.2.101.3 | Note | E | insert the word "the" before "LIGHT ION BEAM DISTRIBUTION SYSTEM' | Add "the" |
| US38 | 1043 | 201.10.2.2.101.3 | a) | T | Wording is unclear. | Revise:  *a) b) site test grade C – Principle: Test each interlock individually. Operate the me equipment under simulated conditions … incorrect values and verify that the interlock performs as intended.* |
| US39 | 1051 | 201.10.2.2.101.3 | c) | E | “system” should be plural | Add an "s" to "system" |
| US40 | 1053 | 201.10.2.2.101.3 | c) | E | End sentence with period | Add period |
| US41 | 1063 | 201.10.2.2.101.3 | a) | E | Incorrect order of tests | Move this test to beginning of list on line 1043. |
| US42 | 1097 | 201.10.2.2.101.5 |  | T | Clarify that initiation shall be prevented, and irradiation shall be terminated if the condition exits. | Revise:  An interlock shall prevent initiation of irradiation … radiation head, and shall terminate irradiation if such a device is inserted. |
| US43 | 1108 | 201.10.2.2.101.5 |  | E | Revise for consistency with requirement. | Revise:  *Type test grade A – statement regarding the means used to ensure compliance. Demonstrate through analysis that the interlock performs as intended.* |
| US44 | 1112 | 201.10.2.2.101.5 |  | T | Compliance test requires intervention and should be grade C. | *SITE TEST grade C – Principle: verify that the INTERLOCK is functioning properly.* |
| US45 | 1140 | 201.10.2.2.102.1 | 1) | E | Clarify wording | Revise:  Initiation of light ion beam irradiation shall be prevented if the … |
| US46 | 1156 | 201.10.2.2.102.1 | a) | T | Insert a type test for clause a. | Insert:  *Type test grade A – statement regarding the means used to ensure compliance. Demonstrate through analysis that the interlock performs as intended.* |
| US47 | 1165 | 201.10.2.2.102.1 | d) | E | Revise for clarity | Revise:  *Type test grade C –* *If the lsd(s) is capable of providing multiple thicknesses or multiple scan patterns, verify that selection of the lsd thickness or scan pattern is required and that the specified lsd thickness or scan pattern is displayed at the tcp.* |
| US48 | 1174 | 201.10.2.2.102.2 | a) | E | Use defined acronym | change "a RANGE MODULATING DEVICE" to "an RMD" |
| US49 | 1178 | 201.10.2.2.102.2 |  | E | Inconsistent formatting | Do not indent (hang) subsequent lines |
| US50 | 1181 | 201.10.2.2.102.2 |  | E | inconsistent formatting | Do not indent (hang) subsequent lines |
| US51 | 1230 | 201.10.2.2.102.3 | b) | E | Clarify wording | Revise:  b) initiation of irradiation shall be prevented or irradiation shall be terminated … |
| US52 | 1258 | 201.10.2.2.102.3 | b) | T | Insert a site test | Add:  *b) site test grade C – Principle: verify that the monitoring system(s) is functioning properly.* |
| US53 | 1261 | 201.10.2.2.102.3 | d) | T | This test should be performed on each piece of equipment. | Change to a site test grade B |
| US54 | 1275 | 201.10.2.2.102.4 | c) | E | Incorrect grammar | “For a) and b)…” |
| US55 | 1282 | 201.10.2.2.102.4 | a) | T | Add a site test. | Add:  *a) site test grade C – Verify that the position of the applicator carriage is displayed before and during irradiation.* |
| US56 | 1286 | 201.10.2.2.102.4 | b) | E | This test should be listed before the previous one. | Change the order of the tests. |
| US57 | 1288 | 201.10.2.2.102.4 | b) | E | Extra period | Delete extra period |
| US58 | 1290 | 201.10.2.2.102.4 | b) | E | A comma appears at the end of the sentence. | Change comma to a period. |
| US59 | 1301 | 201.10.2.2.102.5 | b) | E | “Portal” is a defined term | Change to small capitals |
| US60 | 1318 | 201.10.2.2.102.5 | a) | T | This test should be performed on each piece of equipment.  Revise for clarity | Change to a site test grade B.  Revise:  Verify that … displayed before irradiation or, for segmented irradiation, before each segment. |
| US61 | 1340 | 201.10.2.2.102.6 | c) | E | Revise for clarity. | Replace “is not in the correct position” with “is not properly attached”. |
| US62 | 1343 | 201.10.2.2.102.6 | d) | E | Revise for clarity.  This subclause contains two requirements and should be separated into two subclauses. | Replace “is not in the correct position” with “is not properly attached”.  Move the second sentence to a new subclause e). |
| US63 | 1356 | 201.10.2.2.102.6 | b) | T | This is the test for subclause c) and must be changed. | Revise:  *b) site test grade B – Verify that …* *cannot be started if the installed light ion beam applicator does not match the intended light ion beam applicator.* |
| US64 | 1359 | 201.10.2.2.102.6 | c) | T | This is same test as for subclause d) and must be changed | Revise:  Demonstrate … *is performed before irradiation and that the irradiation cannot be started if it does not match the prescribed position.* |
| US65 | 1363 | 201.10.2.2.102.6 | d) | T | Change to type test grade A and revise for clarity. | Revise:  Type test grade A – Demonstrate by inspection of the technical documentation that a verification of the correct attachment of the light ion beam applicator is performed during irradiation and that irradiation is interrupted if the applicator is no longer correctly attached. |
| US66 | 1366 | 201.10.2.2.102.6 |  | T | A compliance test is needed for the new subclause e) | Add:  *TYPE TEST grade A – If two or more independent systems to monitor the correct attachment of the applicator are not used, verify that an analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.* |
| US67 | 1395 | 201.10.2.2.102.7 | a) | T | The type test should be grade B | Change the test to grade B |
| US68 | 1397 | 201.10.2.2.102.7 | a) | T | A site test is needed. | Add a site test grade B |
| US69 | 1398 | 201.10.2.2.102.7 | b) | T | The site test should be grade B | Change the test to grade B |
| US70 | 1411 | 201.10.2.2.102.8 |  | E | “patient” is a defined term. | Write in small capitals. |
| US71 | 1415 | 201.10.2.2.102.8 |  | E | “patient” is a defined term. | Write in small capitals. |
| US72 | 1423 | 201.10.2.2.102.8 | a) | E | ACCESSORY should be plural | change to "ACCESSORIES" |
| US73 | 1427 | 201.10.2.2.102.8 | b) | E | ACCESSORY should be plural | change to "ACCESSORIES" |
| US74 | 1432 | 201.10.2.2.102.8 | d) | E | ACCESSORY should be plural | change to "ACCESSORIES are" |
| US75 | 1435 | 201.10.2.2.102.8 | e) | E | ACCESSORY should be plural | change to "ACCESSORIES" |
| US76 | 1441 | 201.10.2.2.102.8 | a) | E | ACCESSORY should be plural | change to "ACCESSORIES are" |
| US77 | 1445 | 201.10.2.2.102.8 |  | E | ACCESSORY should be plural | change to "ACCESSORIES are" and "are not the selected ACCESSORIES." |
| US78 | 1441 | 201.10.2.2.102.8 |  | E | should apply to each ACCESSORY | change to "...*analysis that verification of each accessory position is performed during irradiation and that the irradiation would be stopped in case any accessory becomes improperly affixed."* |
| US79 | 1460 | 201.10.2.2.102.8 | b) d) | E | The compliance test should use defined terms and should use correct grammar. | Revise as: “Verify …cannot be initiated unless the user-installed accessories are correctly affixed and are the selected accessories. |
| US80 | 1465 | 201.10.2.2.102.8 | e) | E | The compliance test should use defined terms and should use correct grammar. | Revise as: “Demonstrate … irradiation would be terminated if any accessory were to become improperly affixed |
| US81 | 1553 | 201.10.2.2.103.1.2 |  | E | SYSTEMS should be singular | change to SYSTEM |
| US82 | 1598 | 201.10.2.2.103.1.3 | a) | T | Test is incomplete. | Add: Demonstrate that at least one of the BFDMs is located on the PATIENT side of all  LATERAL SPREADING DEVICES and that it is a transmission type. |
| US83 | 1650 | 201.10.2.2.103.1.5 |  | E | The title is incorrect; I is the dose monitoring information that should be displayed, not the system. | Add “information” at the end of the title. |
| US84 | 1650 | 201.10.2.2.103.1.5 |  | E | This clause and the following clause should be reversed, so that the reader does not have to jump ahead to determine what information to display. | Change the order of clauses 201.10.2.2.103.1.5 and 201.10.2.2.103.1.6 |
| US85 | 1654 | 201.10.2.2.103.1.5 |  | E | period should not be strikethrough format | do not use strikethrough |
| US86 | 1655 | 201.10.2.2.103.1.5 |  | E | A note is needed to provide examples | Add a Note: Examples of appropriate displays include left/right and up/down ratios for beams spread laterally by scatterers and spot delivery locations versus spot prescribed locations for modulated scanning beams. |
| US87 | 1733 | 201.10.2.2.103.1.7 |  | E | add commas to set off clause | add commas |
| US88 | 1742 | 201.10.2.2.103.1.7 |  | E | should "IRRADIATIONS" be changed to "each IRRADIATION"? | Means shall be provided to ensure that the system that has not caused TERMINATION OF  IRRADIATION is tested ~~between, or~~ prior to~~,~~ each IRRADIATION~~S~~ to verify its capability to TERMINATE IRRADIATION. |
| US89 | 1770 | 201.10.2.2.103.1.8 | a) | E | An incorrect term is used. | Revise to read: “…shall be available for TERMINATION OF IRRADIATION using preset values.” |
| US90 | 1786 | 201.10.2.2.103.1.8 | b)5) | T | The expression “pre-determined number of counts” is not sufficiently clear, and might be specific to a certain type of equipment. | protect against failure of the DOSE MONITORING SYSTEMS by TERMINATING IRRADIATION when a quantity related to dose reaches a pre-determined level. |
| US91 | 1791 | 201.10.2.2.103.1.8 | b)7) | E | "segments" is too arbitrary a term. | Change "segments" to "each segment" |
| US92 | 1798 | 201.10.2.2.103.1.8 | c) | E | Incorrect indentation | This paragraph should be aligned with b) above. |
| US93 | 1807 | 201.10.2.2.103.1.8 | a) | T | The application of this type test to all three paragraphs is confusing, and unnecessary, as paragraphs b) and c) have explicit type tests. | Delete “to c)” |
| US94 | 1831 | 201.10.2.2.103.1.8 | c) | T | The type test is incomplete. | Add “…and that a detailed explanation of the relationship to dose is included.” |
| US95 | 1843 | 201.10.2.2.103.1.9 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US96 | 1848 | 201.10.2.2.103.1.9 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US97 | 1887 | 201.10.2.2.103.1.9 | d) | T | Tests are in the wrong order. Also, the test is incomplete as written. | Move to 1877, Revise: “Confirm that the value of the excess ABSORBED DOSE is given in the technical description.” |
| US98 | 1990 | 201.10.2.2.103.4 | a) | T | Test is intended to apply to the TCP as well as from other locations, so it is better not to be so specific. | Delete “from other locations” |
| US99 | 2026 | 201.10.2.2.103.5 | b) | T | Applying this requirement to all operating parameters is too far-reaching. It should only apply to those parameters that can be changed by the operator. | Add: “…user modifiable” before “operating parameter” |
| US100 | 2034 | 201.10.2.2.103.5 |  | E | There must be redundant sensors for each movement. | Insert: “for each possible movement” after “sensors” |
| US101 | 2060 | 201.10.2.2.103.6 |  | E | Incorrect punctuation | Change period to a comma |
| US102 | 2082 | 201.10.2.2.103.6 | b) | E | Order of tests is incorrect. | Type test should appear before site test |
| US103 | 2089 | 201.10.2.2.103.7 | Title | E | The term: GATING SIGNALS is not the correct defined term. | Defined term is “BEAM GATING SIGNALS” |
| US104 | 2091 | 201.10.2.2.103.7 |  | E | There is not necessarily a single beam gating function. | If a BEAM GATING… |
| US105 | 2134 | 201.10.2.2.104.1 | a) | E | Incorrect word | Change “within” to “in” |
| US106 | 2143 | 201.10.2.2.104.1 | b) |  | Incorrect word | Change “within” to “in” |
| US107 | 2176 | 201.10.2.2.104.2 | a) |  | Incorrect word | Change “within” to “in” |
| US108 | 2205 | 201.10.2.2.104.2 |  | E | Should make consistent with other clauses and allow LIGHT ION RANGE | add "or LIGHT ION RANGE" |
| US109 | 2238 | 201.10.2.2.104.3 |  | T | Include paragraph d) in compliance test. | Revise: “a) to d)” |
| US110 | 2329 | 201.10.2.2.105.2 |  | E | Comma should be removed in clause title | delete comma |
| US111 | 2364 | 201.10.2.2.105.2 |  | E | Should be LIGHT ION ENERGY PER NUCLEON | add "PER NUCLEON" |
| US112 | 2381 | 201.10.2.2.105.3 |  | E | Change dash to colon to be consistent | replace dash with colon |
| US113 | 2413 | 201.14.101 |  | E | Sentence is awkward | Add a comma after “PESS”. |
| US114 | 2462 | 201.17 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US115 | 2466 | 201.17 |  | E | Reverse text in defined term. | LIGHT ION BEAM MEDICAL EQUIPMENT |
| US116 | 2575 | Annex B |  | E | need to insert the word "it" after the word "if" | add the word "it" |