

**IEEE 802
Local and Metropolitan Area Network Standards Committee**

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cell: 857.205.0050**

To: Charles S. Farlow

CC: Karen McCabe , Tricia Gerdon

SUBJECT: Appeal Brief, IEEE 801.15.6 Decisions

DATE: March 16, 2012

Dear Mr Farlow:

Please find attached our response to your Appeal Brief of Jan 20, 2012. The response takes the form of embedded text after each of your points.

We are in the process of forming an Appeal Panel. You will be asked to approve of at least two members of that panel. The panel is scheduled to meet during the 802 Plenary Session in San Diego this coming July.

Please let us know if you have any questions or comments.

Regards,

Paul Nikolich

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January 20, 2012

Mr. Paul Nikolich
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Subject: Appeal Brief, IEEE 801.15.6 Decisions

Dear Paul,

This letter constitutes an Appeal Brief for two recent decisions related to draft standard IEEE 802.15.6 (Body Area Networks): a) 22 Dec. 11 EC decision to submit the draft to RevCom, and b) 21 Dec. 11 decision of the IEEE 802.15.6 Ballot Resolution Committee (BRC) for comments r03-03, r03-04, r03-05, and r03-06.

1. The "Resolution Detail" of "Group can not reach concensus." for four rejected comments (r02-06, r02-07, r02-08, r02-09) as documented in 15-11-0868-01-0006 is not valid.

Ignoring, for the moment, the spelling error, the text entered in the "Resolution Detail" field for comments r02-06, r02-07, r02-08, r02-09 is a status of Ballot Resolution Committee's deliberation, not a "resolution" in any sense of the word. The "Resolution Detail" does not provide any feedback to the commenter. There is no allowance for this type of response in in any IEEE-SA policy or procedure.

[Response: Section 5.4.3.3 of the SASB Operations Manual states:

The Sponsor shall consider all comments that are received by the close of the ballot. Comments received after the close of balloting will be provided to the Sponsor. The Sponsor shall acknowledge the receipt of these late comments to the initiator and take such action as the Sponsor deems appropriate.

The Sponsor shall make a reasonable attempt to resolve all Do Not Approve votes that are accompanied by comments. Comments that advocate changes in the proposed standard, whether technical or editorial, may be accepted, revised, or rejected.

The sponsor has an obligation to consider all comments and make a reasonable attempt to resolve these them. It does not mean that in all cases it must arrive at a definitive resolution. In this case the committee that was tasked to consider these comments was unable to agree to on the merits of the comments and so indicated that in its resolution. Since no agreement could be reached the draft was left unchanged and the comments listed as rejected; the only available choice among the three choices. The ultimate authority is the Sponsor Balloting Group, which is the consensus body, not this committee. The balloting group was presented with the comments and the resolution and sustained the no change action.]

2. Selected IEEE 802.15.6 Ballot Resolution Committee (BRC) voting results exceeded a 30% abstention rate; therefore, these BRC votes are not valid.

IEEE 802.15.6 BRC voting results exceeded a 30% abstention rate for r02-06, r02-07, r0208, and r02-09 comments as documented in 15-11-0872-01-0006. Paragraph 5.4.3.5 of the IEEE-SA Standards Board Operations Manual states “In the event that 30% or more of the returned ballots are *Abstentions*, the standards balloting process shall be considered invalid.” Notwithstanding the IEEE-SASB Operations Manual’s requirement, in one case, the number of “Abstentions” equaled the sum of “Yes” and “No” votes (e.g., r02-06, Yes: 4, No: 2, Abstain: 6.). Clearly, this vote is not valid by any modern standards development metric.

[Response: The 30% abstention rate rule applies to the Sponsor Ballot itself not the work of the committee.]

3. IEEE 802.15.6 TG6 PAR paragraph 7.3 was not updated as required by the IEEE-SA Standards Board Operations Manual.

The IEEE 802.15.6 TG6 PAR, paragraph 7.3, was not updated to reflect the safety concerns expressed by the Advanced Medical Technology Association, European Telecommunications Standards Institute (ETSI), and ISO/TC 150/SC 6 - IEC/SC 62D JWG

1. As stated in paragraph 5.2 of the IEEE-SA Standards Board Operations Manual, “It is important for standards-writing committees to examine the approved PAR periodically in order to make certain that its information is current as shown on the form. This will minimize delays in obtaining approval of final submittals.”

[Response: First, the vast majority of, the Working Group, and then the Sponsor Balloting Group did not agree that there were safety concerns and therefore the issue of updating the PAR was mute. Second, this section of the PAR is not material since the PAR is not the normative document. Third, and independently of the PAR, the draft was submitted for two reviews by IEEE SA legal to ensure that these issues were handled in the appropriate manner. All recommendations made by legal were incorporated in the draft and verified by IEEE SA staff.]

4. Four rejected comments (r03-03, r03-04, r03-05, r03-06) and their predecessors were not addressed with sufficient technical rigor, as evidenced by the lack of documentation indicating serious consideration of said comments.

This comment is self-explanatory; many comments submitted during the Sponsor Ballot phase received little consideration by proponents of Clause 11 technology. Particularly, for r03-03, r03-04, r03-05, r03-06 (and predecessor comments), proponents of the technology specified in Clause 11 refused to provide any technical justification in their response(s). As stated in paragraph 5.4.3.3 of the IEEE-SA Standards Board Operations Manual, “Sponsors shall provide evidence of the consideration of each comment via approved IEEE Standards Association balloting tools.”

[Response: The Balloting Group was formed under IEEE SA guidelines and as such it was balanced and represented a broad cross section of relevant technical expertise. All

rejected comments, regardless of the reason, were provided to the Ballot Group for their consideration via approved IEEE SA balloting tools. Evidence of that can be found in the MyProject system. These are the same documents you should have received as a member of the balloting group but can be provided to you again if needed.]

5. The conditional approval of draft standard IEEE 802.15.6 is not consistent with the IEEE Code of Ethics.

In the IEEE Code of Ethics (first paragraph) members agree “to accept responsibility in making decisions consistent with the safety, health, and welfare of the public, and to disclose promptly factors that might endanger the public or the environment.” Faced with three letters indicating a risk to patients with Active Implantable Medical Devices (AIMDs), the IEEE 802 Executive Committee (EC) still provided conditional approval of the draft IEEE 802.15.6 standard. The conditional approval of draft standard IEEE 802.15.6 is not consistent with the IEEE Code of Ethics nor does the IEEE 802 EC possess the medical expertise required to render a valid decision.

[Response: The 802 Executive Committee makes its decision on whether to forward a draft to RevCom based on whether Policy and Procedure has been correctly followed, not on the content of the draft or the content of the comments on the draft. The Balloting Process itself is for weighing the merits of the various positions. Therefore the Balloting Group is responsible body for making decisions consistent with the safety, health, and welfare of the public. As long as that process has been followed, the EC is satisfied. In this case, not only was the EC presented with compliance with process, but also with the fact that the draft had received two legal reviews and complied with all recommendations of both. It is fair to say the EC acted responsibly.]

If there are any questions related to this appeal, please contact me at charles.s.farlow@medtronic.com (+1 763 742 5158).

Respectfully,

// submitted electronically //

Charles S. Farlow

cc: Richard Hulett, Chair, Standards Board, IEEE Standards Association Bob Heile, Chair IEEE 802.15 Art Astrin, Chair IEEE 802.15.6