

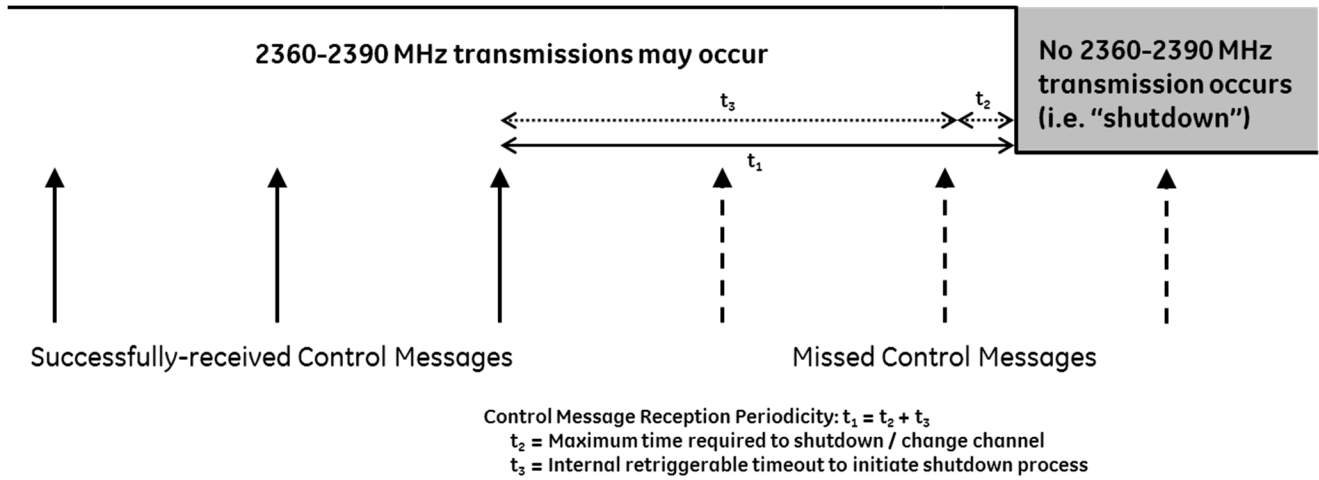
In the Matter of )  
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Part 95, Medical Body Area Network )  
(MBAN) Measurement Procedure )  
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GE Healthcare (“GEHC”), Philips Healthcare (“Philips”), and the Aerospace and Flight Test Radio Coordinating Council, Inc. (“AFTRCC”) (collectively, the “Joint Parties”) hereby submit these comments in response to the October 15, 2015 Draft Publications Report (“Draft Publications Report”) released by the Commission’s Office of Engineering and Technology (“OET”) Laboratory Division.<sup>1</sup> The Draft Publications Report proposes guidance on the procedures to be used in demonstrating compliance with the Medical Body Area Network (“MBAN”) requirements contained in Part 95 of the Commission’s rules.<sup>2</sup> The Joint Parties propose the following measures to ensure that MBAN devices operate as expected.

<sup>1</sup> See *Medical Body Area Network (MBAN) Measurement Procedures*, Draft Laboratory Division Publications Report, 670572 D01 MBAN v01 (OET, rel. Oct. 15, 2015) (“Draft Publications Report”), available at <https://apps.fcc.gov/eas/comments/GetPublishedDocument.html?id=395&tn=433449>.

<sup>2</sup> See *id.*

**Second**, the term “control message receive periodicity” should be defined as “the maximum time between reception of the last valid control message and termination of transmission in the 2360-2390 MHz band. This time includes any sleep time and radio control latency that may be internal to the MBAN transmitter.” See Figure 1.



*Figure 1: Timing diagram illustrating relationship between Control Message Receive Periodicity and shutdown latency.*

**Third**, certification applicants should be required to describe how the control message is distributed to all MBAN devices within a healthcare facility (indoors only).

**Fourth**, certification applicants should be required to specify whether the MBAN system includes any alternative or back-up mechanisms to ensure shutdown within whatever time period is coordinated for a given deployment, and if so, to state what those alternative(s) are and how they work operationally, including related timing diagrams.

**Fifth**, because MBAN devices are expected to rely on software to implement the requirements of Section 95.628(c) of the Commission’s rules to ensure that safety-of-life

Aeronautical Mobile Telemetry (“AMT”) systems are protected from harmful interference,<sup>3</sup> an increased level of rigor with respect to software is warranted in the Commission’s MBAN equipment certification process in order to assure software reliability.<sup>4</sup>

In particular, the certification process should 1) require attestations regarding the methods used throughout the software development lifecycle (*e.g.*, compliance with process standards such as IEC 62304, as is recognized by the Food and Drug Administration) to assure software quality and reliability with respect to functionality that could impact compliance with the Commission’s rules; and 2) ensure testing that sufficiently exercises<sup>5</sup> the operational domain of MBAN software control functionality. For example, such testing should include testing: (1) with various combinations of channels enabled and disabled to ensure the transition from one combination to another occurs correctly; and (2) that ensures that automatic vacating of 2360-2390 MHz occurs reliably within the expected timeframe under a variety of initial conditions, including various values of receive periodicity, if configurable. The Commission should consider objective evidence (*i.e.*, detailed test procedures and results) of such rigorous verification activities submitted by a proposed MBAN device vendor in lieu of performing all such testing at the testing laboratory.

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<sup>3</sup> See 47 C.F.R. § 95.628(c).

<sup>4</sup> In addition to testing in order to assure sufficient dependability of high consequence software, quality assurance measures must also be employed throughout the software development lifecycle to prevent and detect defects. See, *e.g.*, David L. Parnas, A. John van Schouwen, and Shu Po Kwan, *Evaluation of Safety-Critical Software*, 33 Communications of the ACM, 636-658 (1990); Bev Littlewood and Lorenzo Strigini, *Software Reliability and Dependability: a Roadmap*, In Proceedings of the Conference on the Future of Software Engineering, 175-188 (2000); Lynnette I. Millet, Martyn Thomas, and Daniel Jackson, eds., *Software for Dependable Systems: Sufficient Evidence?*, National Academies Press (2007); Kuhn, D. Richard, Raghu N. Kacker, and Yu Lei, *Practical Combinatorial Testing*, National Institute of Standards and Technology Special Publication 800-142 (2010).

<sup>5</sup> For example, rather than testing only 2-3 cases, as would typically suffice for hardware, in order to establish confidence that software behavior will consistently conform to applicable requirements, software testing needs to exercise a significant set of distinct inputs and operating conditions according to statistical, combinatorial, or other objective criteria. See *id.*

*Finally*, as a condition of coordination, certification applicants should be required to certify to the MBAN frequency coordinator that the specific MBAN deployment has been tested to confirm device shutdown within the time period for which the site has been coordinated.<sup>6</sup>

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<sup>6</sup> Proper installation is important to the functioning of MBAN systems in accordance with the Commission's rules. The Joint Parties addressed this matter in their February 6, 2014 *ex parte* letter. *See* Letter from Ari Q. Fitzgerald, Counsel, GEHC, et al., to Marlene H. Dortch, Secretary, FCC, ET Docket No. 08-59 (filed Feb. 6, 2014). While not an equipment certification matter, it is noted here given its bearing on MBAN rule compliance with the 2360-2390 MHz indoor operation restriction. *See also Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks*, Order on Reconsideration and Second Report and Order, 29 FCC Rcd 10662 ¶ 49 (2014).