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**P2864**

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**Submitter Email:** c.carey@ieee.org  
**Type of Project:** New IEEE Standard  
**Project Request Type:** Initiation / New  
**PAR Request Date:** 06 Jan 2020  
**PAR Approval Date:** 04 Mar 2020  
**PAR Expiration Date:** 31 Dec 2024  
**PAR Status:** Active

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**1.1 Project Number:** P2864  
**1.2 Type of Document:** Guide  
**1.3 Life Cycle:** Full Use

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**2.1 Project Title:** Guide for a Software Change Control System for Three-Dimensional (3D) Bioprinting of Tissue-Engineered Medical Products (TEMPs)

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**3.1 Working Group:** Three-Dimensional (3D) Bioprinting of Tissue-Engineered Medical Products (TEMPs) (EMB/Std Com/3D-B TEMPs)

**3.1.1 Contact Information for Working Group Chair:**

**Name:** Becky Robinson-Zeigler  
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**3.1.2 Contact Information for Working Group Vice Chair:**

**Name:** Lexi Garcia  
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**3.2 Society and Committee:** IEEE Engineering in Medicine and Biology Society/Standards Committee(EMB/Std Com)

**3.2.1 Contact Information for Standards Committee Chair:**

**Name:** Carole Carey  
**Email Address:** c.carey@ieee.org

**3.2.2 Contact Information for Standards Committee Vice Chair:**

**Name:** Hasan Al-Nashash  
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**3.2.3 Contact Information for Standards Representative:**

**Name:** Carole Carey  
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**4.1 Type of Ballot:** Individual

**4.2 Expected Date of submission of draft to the IEEE SA for Initial Standards Committee Ballot:** Apr 2021

**4.3 Projected Completion Date for Submittal to RevCom:** Oct 2021

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**5.1 Approximate number of people expected to be actively involved in the development of this project:** 15

**5.2 Scope of proposed standard:** This document provides guidelines for how to develop and implement a software change control system to manage all changes made during three-dimensional (3D) printing of medical products to create tissues or tissue-like structures (bioprinting) for transplantation into an animal or human, and/or anatomic modeling purposes. The change control system will provide a process to ensure that the changes made to the product are introduced in a controlled manner.

**5.3 Is the completion of this standard contingent upon the completion of another standard?** No

**5.4 Purpose:** To establish guidance for accurate and optimized software change code procedures for TEMPs and anatomic modeling development via 3D bioprinting.

**5.5 Need for the Project:** Bioprinting has technological challenges that do not exist in other industries, such as the use of living cells during printing, which necessitates manufacturing materials and resources that are biocompatible and non-toxic. A software change control system is needed to improve the safety and quality of the printed medical product by minimizing unnecessary changes and documenting all changes, so that product manufacturing is not unnecessarily disrupted and materials are used efficiently.

**5.6 Stakeholders for the Standard:** Medical practitioners, health care managers, medical researchers, TEMP developers, technical experts, 3D bioprinting companies, medical imaging equipment manufacturers, 3D biomaterials and ink manufacturers, 3D devices manufacturers, including 3D monitor and 3D display

panel manufacturers.

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**6.1 Intellectual Property**

**6.1.1 Is the Standards Committee aware of any copyright permissions needed for this project?**

No

**6.1.2 Is the Standards Committee aware of possible registration activity related to this project?**

No

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**7.1 Are there other standards or projects with a similar scope?** No

**7.2 Is it the intent to develop this document jointly with another organization?** No

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**8.1 Additional Explanatory Notes :**