P3333.2.5.5

Submitter Email: ylm2103@gmail.com
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Status: PAR for a New IEEE Standard
Project Record: P3333.2.5.5

1.1 Project Number: P3333.2.5.5
1.2 Type of Document: Standard
1.3 Life Cycle: Full Use

2.1 Title: Standard for In Vivo Evaluation of 3D Printed Polymeric scaffolds in bone defects

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3.1 Working Group: 3D Based Medical Application Working group (EMB/Stds Com/3333.2)
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3.2 Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society/Standards Committee (EMB/Stds Com)
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None

4.1 Type of Ballot: Individual
4.2 Expected Date of submission of draft to the IEEE-SA for Initial Sponsor Ballot: 03/2021
4.3 Projected Completion Date for Submittal to RevCom
Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 10/2021

5.1 Approximate number of people expected to be actively involved in the development of this project: 40
5.2 Scope: This document specifies the in vivo examination required for the biological assessment of three-dimensional (3D) bio-printed polymeric scaffolds intended for use in bone regeneration. 3D bio-printed scaffolds are gaining increased attention and animal experiments are fundamental in assessing their performance prior to potential clinical use. In vivo assessment will include the following features. Animal model include rat or rabbit. Bone defect can be created on the skull, femur or pelvis. The defect size is minimum 5mm3 in volume. Assessment include histopathological, radiological and mechanical assessment.

5.3 Is the completion of this standard dependent upon the completion of another standard: No
5.4 Purpose: As with other implant materials, 3D bioprinted scaffolds need to be evaluated within proper animal models prior to potential clinical use. This protocol defines the criteria that should be met in order to conduct these experimentation.

5.5 Need for the Project: Bone can heal itself in case of damage, however, regeneration is not always complete. Defects may be left unrepaired in case of large defects such as bone tumor resection. Such cases are common and defects should be filled with proper bone fillers in order to achieve structural and mechanical support. An ideal bone filler should be composed of an osteoconductive matrix that allows bone regeneration and ingrowth, osteoinductive agents that induce regeneration, and osteogenic cells that form bone formation centers. Among all the bone fillers used in the clinic the only one with all the desired properties is autografts and is used as a golden standard. However, problems such as donor site morbidity and limited availability limits the use of autografts. Other bone fillers lack osteoinductivity and/or osteogenicity as well as having their own limitations; therefore, new techniques were searched for the production of bone substitutes. Tissue engineering is considered to be a promising and developing field for the production of bone tissue that would eventually replace bone grafting. The strategy of

bone tissue engineering involves the isolation of healthy cells from the defect site that are then seeded on biodegradable scaffolds that structurally and mechanically mimics the defect site. After in vitro mineralization and maturation, the construct is transplanted to the defect site. 3D bioprinting is achieving increased attention in the production of tissue engineering scaffolds owing to the possibility of creating anatomically-shaped scaffolds with precise control over the internal architecture to maximize the structural and mechanical fit as well as to control the cellular behavior.
Medical Bio 3D Printing has high technological barriers, which do not necessarily exist in other industries. Bio Medical 3D Printer requires high reliability in producing useful and cost-effective products leading to the market and process standardization of 3D solutions to various requirements.

5.6 Stakeholders for the Standard: 3D Printer Manufacturers
Bio 3D Printing filament (material) manufacturers
Medical Imaging Equipment Manufacturers
S/W programmers for 3D volume imaging Medical practitioner
Health care manager
Medical researcher
Medical device developer
Technical expert
3D product manufacturer

Intellectual Property
6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: No
6.1.b. Is the Sponsor 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 Joint Development
Is it the intent to develop this document jointly with another organization?: Yes
Organization: ISO
Technical Committee Name: Additive manufacturing
Technical Committee Number: TC 261
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8.1 Additional Explanatory Notes: