Reporting documents

Evidence of contributions to new or improved national and international guides, recommendations, standards and guidelines with a specific focus on, to be submitted e.g. to ISO/TC261, CEN/TC438, ISO/TC213

Examples of early uptake of project outputs by end users

Deliverable D9

Lead author: LNE

Project 15HLT09 “MetAMMI Metrology for additively manufactured medical implants”.

Due date: 31st May 2019

Submission date: 4rd June 2019



**Content**

[1 Involvement in Standards Committee / Technical Committee / Working Group 3](#_Toc10531192)

[2 Standards and technical committees/working goup on additive maufacturing: ISO/TC261-AM, UNM920-AM (France) 3](#_Toc10531193)

[2.1 BAM 3](#_Toc10531194)

[2.2 LNE 3](#_Toc10531195)

[3 Standards and technical committees/working goup on X-ray computed tomography: ISO/TC213 WG10-XCT task force, VDI/VDE-GMA FA 3.33-XCT (Germany) 4](#_Toc10531196)

[3.1 PTB 4](#_Toc10531197)

[3.2 FAU 5](#_Toc10531198)

[4 Standards and technical committees/working goup on surface texture: ISO 213 WG16 GPS 5](#_Toc10531199)

[4.1 UNOTT 5](#_Toc10531200)

# Involvement in Standards Committee / Technical Committee / Working Group

|  |  |  |
| --- | --- | --- |
| **Standards Committee / Technical Committee / Working Group** | **Partners involved** | **Likely area of impact / activities undertaken by partners related to standard / committee** |
| ISO/TC261-AM | BAM | The ISO/TC 261-AM WG meets annually. BAM is a member of the WG's WG1: “terminology” and WG2: “Processes, methods and materials”. BAM will provide input on terminology, process and methods. This will enable improved standards for the medical device industry. |
| UNM920-AM | LNE | The UNM920-AM meets twice a year. LNE is a member of this French national group and will provide input on the characterisation of parts as well as the more appropriate techniques to choose depending of the parts as well as on the level of accuracy. This will enable standards to be written. |
| ISO/T 261-ASTM F42-AM | LNE | The ISO/T 261-ASTM F42-AM JWG 59 meets annually. LNE is a member if this WG and will provide input on NDT. This will enable a guide to be written. |
| ISO/TC213 WG10 XCT task force | PTB | The ISO/TC 213 WG 10 meets twice per year. PTB is a member of this WG. One working item is the standard ISO 10360-11 about acceptance and reverification testing of coordinate measuring systems using CT sensors (industrial CT systems). PTB is co-leader of the task-force XCT and will provide input, in particular regarding CT measurements of parts with rough surfaces. This will enable CT measurements of parts with rough surfaces to be taken into account during the work item for the standard. |
| VDI/VDE-GMA FA 3.33-XCT | PTB, FAU | VDI/VDE-GMA FA 3.33 meetings are held every six months. PTB and FAU are members. Results from this project will be presented at the meetings on a regular basis. This will enrich the standards that the group is presently working on. |
| ISO 213 WG16 GPS | UNOTT | ISO 213 WG 16 GPS Surface texture – meets twice per year to develop standards for surface texture measurement and characterisation. UNOTT is a member of this WG. Also holds regular telecoms on optical areal measurement methods. This will enrich the standards that the group is presently working on. |

# Standards and technical committees/working goup on additive maufacturing: ISO/TC261-AM, UNM920-AM (France)

## BAM

BAM is involved in the working committee NA 145-04-01 AA of the DIN standards committee technology of materials (NWT), which works on interdisciplinary topics related to additive manufacturing, such as terminology or software and testing. It is the German mirror committee to the Technical Committees CEN/TC 438 “Additive Manufacturing” and ISO/TC 261 “Additive Manufacturing” including the working groups ISO/TC 261/CAG, WG1 and WG2.

The participation in these standardization activities has recently been resumed. Results achieved within the MetAMMI project will be contributed to relevant standards.

## LNE

The national standards development organization UNM920 (AFNOR) and the international standards development organisations ISO/TC261 and ASTME07 develop standards on various subjects related to additive manufacturing (AM). The MetAMMI-Partner LNE is active in these national and international organisations.

A specific working group of UNM920 on AM in the medical sector developed a French standard during the project period related to “Special requirements to manufacture a medical device” (XP E67-305). LNE has been involved in the writing of this standard. The skills acquired by LNE in the frame of the MetAMMI project enabled LNE to provide inputs to the standard.

A specific joined group JG59 “non-destructive testing (NDT) for AM parts” of the ISO/TC261 is currently developing a technical report on “General principles -- Non-destructive testing of additive manufactured products” (ISO/ASTM DTR 52905:2019-01). The document describes a best practice presenting NDT methods potential to detect AM defects in metal finished parts which are not covered by current standards. The writing of the technical report is finished. The report is in its correction phase. LNE has been involved in the writing and correction of the report but also beforehand in the fabrication, at NIST, of specific specimens, in different materials, with inner typical artificial AM defects which were used to investigate various NDT methods. LNE has investigated several NDT methods (Archimedes, gas pycnometric, eddy current, resonant ultrasound spectroscopy, phased array ultrasonic testing and X-ray digital radiography methods) with these specimens but also with implants and specimens manufactured in the frame of the MetAMMI project and at NIST (spinal implant, lattice structures). All these studies provided inputs to the standardisation group as well as to the MetAMMI project.

The subcommittee 10 “specialized NDT methods” of the task group on “NDT of aerospace materials” of ASTME07 is currently developing a guide entitled “standard guide for non-destructive testing of metal additively manufactured aerospace parts after build”. LNE is also active in this group to provide inputs on NDT and to gain in competence from other experts which is beneficial both to the MetAMMI project and to the standardization group.

# Standards and technical committees/working goup on X-ray computed tomography: ISO/TC213 WG10-XCT task force, VDI/VDE-GMA FA 3.33-XCT (Germany)

## PTB

Working group (WG) 10 “Coordinate Metrology” of ISO TC 213 “Geometrical Product specification” develops international standards about acceptance and reverification tests for coordinate metrology systems (CMS) and standards about the determination of the measurement uncertainty of CMS measurements. The MetAMMI-Partner PTB is active in ISO TC 213 WG10.

The series of standards developed by this working group are ISO 10360 and ISO 15530. After publication, these standards become part of the corresponding European (EN) and national (e.g. DIN) series of standards.

An important topic in ISO TC213 WG 01 is currently the development of ISO 10360-11 describing acceptance and reverification tests for CMS using the principle of computed tomography (CT). This standard shall adapt the principles of acceptance testing (global length measurement error test and local probing test) of tactile and optical CMS to CMS using CT. This concerns e.g. that the length measurement error test shall include effects caused by the material of the measurement object and different penetration lengths. This standard will be important to determine, if a CMS using CT is suitable for the quality control of implants manufactured by AM.

During the development of the standards it turned out, that hole plates are suitable objects for the length measurement error test. A hole plate design, which is inspired by the other parts of ISO 10360 was developed by NMIJ (Japan) and PTB. Plates made of Aluminum and steel have been manufactured and tested.

In the MetAMMI-project, the same hole plate design has been used. Plates made of metal (i.e. Ti), plastic (i.e. ABS), and ceramics (i.e. Al2O3) were manufactured by AM. With these plates we could study the influence of the high roughness and large form deviations, often present in AM parts on the length measurement errors. This allows us to achieve deeper knowledge about the stability of the length measurement error in the future standard IS= 10360-11.

Also in the MetAMMI-project, the task-specific measurement uncertainty of CT systems, for different measurement tasks, was evaluated inspired on the concepts of the ISO 15530-3. The measurement uncertainty evaluation allows us a deeper knowledge about measurement uncertainty estimation with CT and about the applicability of the ISO 15530-3 standard for CMS with CT sensor.

## FAU

VDI/VDE-GMA FA 3.33-XCT (Germany) is a German technical committee for technical guidelines on dimensional metrology using industrial computed tomography systems. It is affiliated with the VDI/VDE-GMA FA 3.31 and therefore, also with the DIN NA 152-03-02 AA committee which is the German committee for coordinate metrology standardisation.

For this reason, the ISO 10360 TC213 WG10 activities are also discussed within the VDI/VDE-GMA FA 3.33 meetings. This meant, in particular, that the topic of structural resolution was discussed several times and the surface topography measurements of additively manufactured specimen from the MetAMMI project provided valuable background for these discussions.

In addition, numerical task-specific measurement uncertainty evaluation according to GUM Supplement 1 is a relevant topic for the VDI/VDE-GMA FA 3.33 and as a result of the discussions within the committee, a new collaborative project has just started in April 2019. The results achieved within the MetAMMI project provided a basis for the project idea. Furthermore, the results will be a good foundation for the work in the new project.

The FAU and PTB attended all committee meetings within the MetAMMI project duration.

# Standards and technical committees/working goup on surface texture: ISO 213 WG16 GPS

## UNOTT

On the 7th and 8th of February 2017, Luke Todhunter from UNOTT attended the 29th ISO/TC 213 meeting for Working Group 16 (areal and profile surface texture) which took place at the Sirata Beach hotel in St. Petersburg, Florida.

One of the main aspects of the meeting revolved around the review of comments given for working drafts of a new standard for profile surface texture, ISO 21920. The new standard aims to mirror the standards for areal surface texture to make the two approaches more comparable, and is comprised of three parts – Part one: Indication of surface texture, Part two: Terms, definitions and surface texture parameters, and Part three: Specification operators. For each part, comments were reviewed by the group and any proposed changes to the drafts were discussed before being accepted or rejected.

In addition to this, several other document changes were presented and discussed. This included a progress report on an ISO 4287 amendment for the revised definition of the XSm parameters, in which the amendment was presented to the group; a progress report on the revision of an old ISO document on the calibration of contact instruments, ISO 12179, in which the main author detailed their latest attempts to extract the information from the old document; a review of a revised version of ISO 25178-2, in which the document changes were presented by the main author and discussed with the group; and a review of an updated draft of ISO 25178-700, in which the document was walked through by the main author and any suggested changes were discussed and agreed upon by the group. As part of this review, two group members gave presentations on step height calibration.