STARLIT

System Technologies for Adaptive Real-time MR Image-guided Therapies

Labeled in ITEA3, a EUREKA cluster

ITEA3 Project Number 16016

D6.1 – Standardization Plan

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Description:	This standardization plan describes how STARLIT partners influence the development of product standards for individual equipment and for the "integrated clinical environment". Active lobbying in trade associations and professional bodies will also be pursued by partners, but these activities are expected to only gain significant momentum after completion of STARLIT. They are therefore not covered in this plan.	

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	PP	Restricted to other programme participants	
	RE	Restricted to a group specified by the consortium	
	CO	Confidential, only for members of the consortium	

DOCUMENT HISTORY

Release	Date	Reason of change	Status	Distribution
V0.1	31 Oct 2017	First draft	Draft	WP members
V0.2	13 Nov 2017	Update with reference standards and partner inputs	Draft	WP members
V0.3	19 Dec 2017	Further updates reflecting status and plans for standards in active maintenance cycles	Concept	WP members
V1.0	12 Jan 2018	Approved by PMT	Final	Consortium and ITEA office

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Glossary

Abbreviation / acronym	Description
AAMI	Association for the Advancement of Medical Instrumentation
ASTM	American Society for Testing and Materials (currently international)
BT	Brachytherapy
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MITA	Medical Imaging & Technology Alliance
MDD/MDR	Medical Device Directive/Regulation
MR	Magnetic Resonance
MRL	Magnetic Resonance – Linear Accelerator integrated system
NEMA	National Electrical Manufacturers Associations (The association of Electrical Equipment and Medical Imaging Manufacturers)
NWIP	New Work Item Proposal
RCM	Risk Control Measure

1. Executive Summary

Market access for medical electrical equipment is strictly regulated in Europe (MDD, to be replaced by MDR in 2020), the US, Canada, China, Japan and elsewhere. Demonstration of compliance with regulations can be supported by the use of product standards, developed by ISO, IEC, ASTM, NEMA and other organizations. These standards can be harmonized and become European Norms, or are considered voluntary consensus standards. In China and Japan, they may be translated into law.

It is extremely important to influence product standards evolution to ensure early adoption of novel technology, such as those developed in STARLIT. Integration of systems and improved workflows for high-precision therapy have already triggered a major revision of all radiation therapy standards. Consortium partners are active in existing product standard maintenance committees, and do also participate in new work item proposals (NWIP). This plan shows the current involvement of partners, and will be updated once new opportunities or needs are identified.

2. Introduction

Development and use of adaptive real-time image-guided therapy delivery systems is subject to medical device regulation requirements. In Europe, applicable law is the Medical Device Directive (2007/47/EC), which will be replaced by the Medical Device Regulation (2017/745/EU) in 2020.

Awareness among the standards community and regulators is rapidly growing to realize that the full deployment of a variety of new applications in image guided therapy will require a well-thought architecture encompassing a variety of facets: functions, communications, security, information, etc. For example, the US FDA has recently released a guidance document on requirements for Interoperable Medical Devices (UCM482649, Sept 2017). This document recognizes the following:
As electronic medical devices are increasingly connected to each other and to other technology, the ability of these connected systems to safely and effectively exchange and use the information that has been exchanged becomes increasingly important. Advancing the ability of medical devices to exchange and use information safely and effectively with other medical devices as well as other technology offers the potential to increase efficiency in patient care.
FDA intends to promote the development and availability of safe and effective interoperable medical devices. FDA is issuing this guidance to assist industry and FDA staff in identifying specific considerations related to the ability of electronic medical devices to safely and effectively exchange information and use exchanged information. This document highlights considerations that should be included in the development and design of interoperable medical devices and provides recommendations for the content of premarket submissions and labeling for such devices.

STARLIT develops technologies for medical systems for treatment, integrating a heterogeneous set of medical and non-medical devices. The concern of public authorities is safety and efficacy, as well as cost-effective use of technology. STARLIT will address the stakeholders in the policy value chain, related to product safety, market access, and clinical efficacy and cost-effectiveness, see Figure 1.

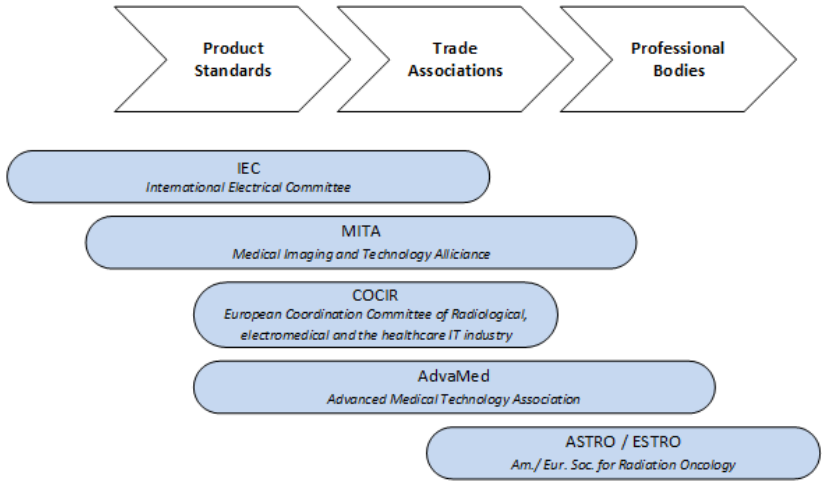

Figure 1: Policy Value Chain for IGRT using Adaptive System of Real-Time Systems.

This standardization plan describes how STARLIT partners influence the development of product standards for devices and for the “integrated clinical environment” (ASTM F-2761). Active lobbying in trade associations and professional bodies will also be pursued by partners, but these activities are expected to only gain significant momentum after completion of STARLIT. They are therefore not covered in this plan.

3. Overview of affected standards

Relevant efforts in contributing to standards will be put by the project partners, according to the ITEA3 strategic guidelines. Open standards will particularly be addressed as well as open source reference implementations.

3.1 Primary standards

Primary standards and technical reports applicable to integrated system development are detailed in Paragraph 3.3.

3.2 Reference standards

Additional standards are relevant to the development of equipment relevant to STARLIT partners in developing and validating new functionality at component and system level.
These standards are not expected to be modified during the STARLIT project. We will collect potential issues in their use and inform associated maintenance teams of potential needs for updates. Such reference standards are listed below:

- ASTM F2052-15
  Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119-07(2013)
  Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2182-11a
  Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
- NEMA RT 1 (2014) Gating Interface
- AAMI RT 2 (2017) Radiation therapy readiness check

3.3 Planning of standards maintenance and development

International Standard	Title	Scope STARLIT relevant topics	Lead Partner *Affected Partner*	Start Date	Stability Date Planned CDV Date
IEC 60601-1 **Ed 3.1 (2012)**	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	7.8.1: indicator lights, in relation to Alarms (IEC 60601-1-6) The priority level is defined by Risk Assessment, but this can be very different for Equipment than for a System. The general standard does not need an update, but this will be considered for D1.2	Philips Elekta	Ed 3.2 2017	**2019** A2: Q2 2018 Ed4: 2022
IEC 60601-1-2 **Ed 4 (2014)**	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Immunity Requirements for Low Frequency Magnetics (<150 kHz). This affects drift or phase stability of the MRI, as well as accuracy of the EBE delivery function. Effects of MRI gradient field outputs (~1 kHz) on other equipment inside the SPECIAL ENVIRONMENT should also be considered, in relation to ASTM WK58852	Philips Elekta	Ed 4.1 2017	**2019** Q2 2018
IEC 60601-2-1 **Ed 3.1 (2014)**	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	4th edition is significantly being restructured and extended, to ensure alignment with the IGRT standard (IEC 60601-2-68). All specific requirements fin sub-clauses 201.101-109 are relevant and including EPID, date and time format, external monitoring devices, latency, interfaces, and position determining devices; and capture requirements for adaptive procedures. Cover interfaces to other standards.	Elekta	Ed 4 2015	**2018** Q3 2017 (WG review Q2 2018)
IEC 60601-2-17 **Ed 3 (2013)**	Medical electrical equipment — Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy	• No immediate changes pertinent to STARLIT innovations will drive an update of the standard. It is foreseen that after STARLIT the following additions will be proposed ○ For HDR treatment in the MRI bore, extra pre-treatment verification for source behaviour and source position in relation to the afterloader. ○ For adaptive MRI guided treatments new requirements for source position and source dwell time control.	Elekta	*unknown*	**2019** Proposed extension of stability date to 2027

International Standard	Title	Scope STARLIT relevant topics	Lead Partner *Affected Partner*	Start Date	Stability Date Planned CDV Date
IEC 60601-2-29 Ed 3 (2009)	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	"Requirements to be complied with by manufacturers in the design and construction of radiotherapy simulators; it does not attempt to define their optimum performance requirements." • Remote movements and mechanical safety • Review and propose implications for MRI-based treatment and required system performance • Work with SC62B CT and MR maintenance teams	Elekta Philips	*Unknown, NWIP*	**2020** *2020?*
IEC 60601-2-33 Ed 3.2 (2015)	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	• Acoustic noise allowed limits for repeated exposures • Thermal dose and CEM43 • Mechanical safety for the patient support • Quench / He exhaust provisions and emergency evacuation	Philips	Ed 4 No formal project yet (2015)	**2017** **2020?**
IEC 60601-2-68 Ed 1 (2014)	Electrical medical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	"It covers procedures to reduce the risk of over-reliance on the X-IGRT EBE systems. For example the manufacturer will provide an interactive interface for user interaction with the correction suggested by the system." STARLIT relevant: • Identify which Risk Control Measures identified for X-ray guided therapy should be applied for the MR Linac and MR guided BT. • Consider if, when and how a non-Xray image guidance standard must be developed (NWIP), relate to PT62926	Elekta	*unknown, update proposal expected*	**2018** not planned
IEC 62083 (2009)	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	• Adaptive and automated planning requirements should be proposed through IEC 62C. These include adaptive treatment planning, inter- and intra-fraction, as well as methods to maintain the treatment/planning records.	Elekta	2016	**2019** 2019?
IEC PT62926	Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy	• Integrated Clinical Environment specialized to IGRT applications with gating and tracking • Reference architecture model with assigned functional responsibilities and managed interfaces	Elekta Philips Modus	2014	(2018) Q2 2018

International Standard	Title	Scope STARLIT relevant topics	Lead Partner *Affected Partner*	Start Date	Stability Date Planned CDV Date
		• Guidance for minimum set of functions to consider in risk assessment • Verification and validation based on motion phantom			
IEC 61217(2011)	Radiotherapy equipment - Coordinates, movements and scales	"applies to equipment and data related to the process of teleradiotherapy, including patient image data used in relation with radiotherapy treatment planning systems, radiotherapy simulators, isocentric gamma beam therapy equipment, isocentric medical electron accelerators, and non-isocentric equipment when relevant. The object of this standard is to define a consistent set of coordinate systems for use throughout the process of teleradiotherapy, to define the marking of scales (where provided), to define the movements of equipment used in this process, and to facilitate computer control when used." • Standard is expected to undergo major changes to adopt modern technologies and workflows; for example what is the implication of isocenter. • STARLIT specific: consider how for example k-space to image transformations and magnet coordinate systems are managed	Elekta Philips *C-RAD*	2017	**2019** 2019? NWIP from US expected
IEC 62274 (2005)	Medical electrical equipment - Safety of radiotherapy record and verify systems	• Proposal for major revision as NWIP, suggested by Elekta • Rename to Radiation Treatment Management System (TMS) • Incorporate closed loop dataflow • Relate to AAMI RT2 – ensure adoption of definition and approaches – relate to T1.2	Elekta	NWIP	2020 Discuss plan Q2 18
IEC 62570 Ed 1 (2014) **ASTM F2503-13**	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	• Improved labelling practice for MR Conditional devices; consider size of symbol in relation to perceived and actual risk • Improved guidance for 'end-user owned' testing and labelling of devices as MR Conditional • (adjacent question:) How is MR Safe/MR Conditional combined with "Linac compatible"?	Philips Elekta NL *Modus* *MR Coils* *IT-V*	2017	2017 Q4 2018

International Standard	**Title**	**Scope** **STARLIT relevant topics**	**Lead Partner** *Affected Partner*	**Start Date**	**Stability Date** **Planned CDV Date**
NEMA MS4 (2010)	Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices	• Develop procedure for quick characterization of average acoustic noise during an examination; extend to other option representative of treatment episodes. • Consider requirement to perform measurement under representative additional noise burden from equipment in/around the MR system	Philips	2015	2019
NEMA MS14	Characterization of RF Coil Heating in Magnetic Resonance Imaging Systems	• Generic standard to ensure safe surface temperatures for RF coils, also applies to MRL or BT compatible RF coils and configurations • Consider potential additional failure modes or other concerns related to electron beam transparent designs or damage	Philips *MR Coils*	2016	2018
ASTM F2761-09 (2013)	Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model	No actions foreseen	none	none	none
ASTM WK58852	Standard Guide for Assessing the Safety of Medical Equipment in the MR Environment	All equipment inside the Special Environment defined by the MR system, but outside the patient bore. • Fixation devices • Cameras • Monitoring devices • Patient support	Philips *Elekta* *Modus* *MR Coils* *IT-V* *C-RAD*	2017	2019
ISO 20417 (TC210/NWIP)	Information to be provided by the manufacturer	Expand scope of EN 1041 to global level; prepare for requirements from MDR and FDA guidance 1500015 on “Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices”	Philips Elekta *Modus* *MR Coils* *IT-V*	2018	2020

International Standard	**Title**	**Scope** **STARLIT relevant topics**	**Lead Partner** *Affected Partner*	**Start Date**	**Stability Date** **Planned CDV Date**
			C-RAD		

4. Conclusions

A set of existing and developing product standards are identified and its development will be actively influenced by the STARLIT consortium. The collaboration of industry and SMEs will facilitate our analysis and proposal of workable and safe solutions in heterogeneous device environments.

Radical changes for RT standards include new clauses dealing with precision therapy and current workflow processes, including adaptive therapy and (real-time) image guidance, system integration, and therapy readiness checks. These requirements will be developed in relation to Task 1.2 in STARLIT.