20 September 2019

Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20201

Re: *Annual Interoperability Standards Advisory (ISA) Review and Comment Period (2019)*

The IEEE Standards Association (IEEE SA) is pleased to submit the following information in response to the above-captioned request for information. We commend the Office of the National Coordinator for Health Information Technology (ONC) in its effort to update the Interoperability Standards Advisory (ISA). As a globally recognized standards developing organization grounded in an open, inclusive, transparent, and consensus-building process, we appreciate the ONC's request for updates to its ISA.

IEEE SA, a globally recognized standards-setting body within IEEE, develops consensus standards through an open process that engages industry and brings together a broad stakeholder community. IEEE standards set specifications and best practices based on current scientific and technological knowledge. IEEE SA has a portfolio of over 1,250 active standards and over 650 standards under development.

IEEE is the world's largest technical professional organization dedicated to advancing technology for the benefit of humanity. Through its highly cited publications, conferences, technology standards, and professional and educational activities, IEEE is the trusted voice in a wide variety of areas ranging from aerospace systems, computers, and telecommunications to biomedical engineering, electric power, and consumer electronics.

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IEEE Standards

The following list includes standards and standards projects that address interoperability focused on healthcare applications, as well as more general interoperability standards that can be applied towards the healthcare domain.

In addition, related standards that provide a baseline for common and interoperable use are also included.

Standard No.	Title	Description	Stakeholders
IEEE P1847	Recommended Practice for Common Framework of Location Services (LS) for Healthcare	A common LBSLS Healthcare framework will (1) improve interoperability between LBSLS product s and other systems, (2) help to avoid costly redundancy of converging LBSLS products, (3) maximize reuse and utility of the functionality of an overall LBSLS system, and (4) improve consumer confidence in LBSLS systems as a standardized offering enabling greater adoption to occur.	RTLS Vendors, Healthcare Systems, Medical
IEEE P2650	Standard For Enabling Mobile Device Platforms To Be Used As Pre-Screening Audiometric Systems	This standard establishes the performance, interoperability and validation requirements of a mobile device platform that typically consists of a mobile phone device in conjunction with a portable or wearable device and associated software, to be used as an audiometric pre-screening device.	Individuals with hearing disabilities Institutional & Individual Care providers
IEEE P2733	Standard for Clinical Internet of Things (IoT) Data and	This standard establishes the framework with TIPPSS principles (Trust, Identity,	Medical device manufacturers, hardware, software and service

	Device Interoperability with TIPPSS - Trust, Identity, Privacy, Protection, Safety, Security	Privacy, Protection, Safety, Security) for Clinical Internet of Things (IoT) data and device validation and interoperability. This includes wearable clinical IoT and interoperability with healthcare systems including Electronic Health Records (EHR), Electronic Medical Records (EMR), other clinical IoT devices, in hospital devices, and future devices and connected healthcare systems.	developers and users for connected healthcare, payers, providers, patients, patient advocates, regulatory.
IEEE P2791	IEEE Draft Standard for Bioinformatics Computations and Analyses Generated by High-Throughput Sequencing (HTS) to Facilitate Communication	This standard establishes accurate and secure communication of bioinformatics protocols in order to facilitate bioinformatic data analysis workflow related exchange and communication between regulatory agencies, pharmaceutical companies, bioinformatics platform providers and researchers. Accurate communication helps ensure responsibility, verify bioinformatics protocol, track provenance information and promote interoperability.	Government bodies and Regulatory Agencies; Medical product manufacturers and their suppliers; Laboratories developing clinical testing protocols; Bioinformatics tool and platform developers who wish to operate in a regulatory environment, including cloud service (PaaS, IaaS, SaaS, FaaS) providers; Peer Reviewers for journals / scientific journal publishers; Public cloud companies operating in the Life Sciences sector including electronic health record (EHR) systems
IEEE P2795	Standard for Shared Analytics Across Secure and Unsecured Networks	This standard identifies the requirements for using shared analytics over secured and unsecured networks. It establishes a consistent method of using an overarching interoperability framework to utilize one or more disparate data systems for analytic purposes without an analytic user having explicit access to or sharing	Organizations that collect, analyze, and share data. This can include government agencies [such as various US organizations including Department of Defense (DoD) and Department of Veterans Affairs (VA) Interagency Program Office (IPO), Defense Health Agency (DHA), Veterans Health Administration (VHA), Food

		the data within these systems. The intent to develop this document jointly with HL7 International Inc.	and Drug Administration (FDA), National Institutes of Health (NIH)] as well as industry groups and academic organizations that would benefit from virtual access to disparate data sets from other entities.
IEEE P2301	IEEE Draft Guide for Cloud Portability and Interoperability Profiles (CPIP)	This guide advises cloud computing ecosystem participants (cloud vendors, service providers, and users) of standards-based choices in areas such as application interfaces, portability interfaces, management interfaces, interoperability interfaces, file formats, and operation conventions. This guide groups these choices into multiple logical profiles, which are organized to address different cloud personalities.	• Cloud consumers • Cloud service providers • Cloud equipment manufacturers • Cloud software developers • Cloud exchange operators • Cloud registration authorities • Governments
IEEE P2302	Standard for Intercloud Interoperability and Federation (SIIF)	This standard defines topology, functions, and governance for cloud-to-cloud interoperability and federation. Topological elements include clouds, roots, exchanges (which mediate governance between clouds), and gateways (which mediate data exchange between clouds). Functional elements include name spaces, presence, messaging, resource ontologies (including standardized units of measurement), and trust infrastructure. Governance elements include registration, geo-independence, trust anchor, and potentially	• Cloud consumers • Cloud service providers • Cloud equipment manufacturers • Cloud software developers • Cloud exchange operators • Cloud registration authorities • Governments

		compliance and audit.	
IEEE P2247.2	Interoperability Standards for Adaptive Instructional Systems (AISs)	This standard defines interactions and exchanges among the components of adaptive instructional systems (AISs). This standard defines the data and data structures used in these interactions and exchanges and parameters used to describe and measure them and establishes requirements and guidance for the use and measurement of the data, data structures, and parameters.	Designers and producers of AIS and related instructional systems; education and training organizations that buy and deploy AIS and other instructional systems; designers and producers of tools used to develop AIS and to author adaptive instructional content; researchers in the fields of learning science and learning engineering; learners who interact with AIS; and the general public that may need to interpret data reported by AIS. Anyone or any organization that produces, buys, or uses an intelligent tutoring system or a personalized learning system is a stakeholder.
IEEE P11073-10316	IEEE Draft Standard Trial-Use Health Informatics - Point-of-Care Medical Device Communication - Device Specialization - Dialysis Device	The purpose of this project is to establish a normative definition of communication between dialysis devices and other medical devices and information systems in a manner that enables plug-and-play interoperability. By providing standardized communication for these devices, information from these systems will be more readily acquired and integrated into the healthcare enterprise information infrastructure, ultimately reducing the cost of implementing such systems and increasing the availability of this class of data.	Renal (dialysis) care providers, dialysis device developers, healthcare informaticists, healthcare technology managers, health information technology specialists, healthcare and medical researchers.

IEEE P11073-10404	IEEE Draft Standard - Health Informatics - Personal Health Device Communication - Part 10404: Device Specialization - Pulse Oximeter	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth pulse oximeter devices and compute engines (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth pulse oximeters.	Individuals who use personal health devices in home and mobile environments, personal health device vendors, personal health compute engine vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE 11073-10406	ISO/IEEE International Standard Health informatics--Personal health device communication Part 10406: Device specialization--Basic electrocardiograph (ECG) (1- to 3-lead ECG)	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal basic electrocardiograph (ECG) devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables	Individuals who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine

		plug-and-play interoperability.	consultants and businesses.
IEEE P11073-10407	IEEE Draft Standard - Health Informatics - Personal Health Device Communication - Device Specialization - Blood Pressure Monitor	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth blood pressure monitor devices and compute engines (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability.	Individuals who use personal health devices in home and mobile environments, personal health device vendors, personal health compute engine vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses
IEEE 11073-10408	ISO/IEEE International Standard - Health Informatics - Personal Health Device Communication Part 10408: Device Specialization - Thermometer	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth thermometer devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability.	Stakeholders are people who use personal health devices in home and mobile environments, personal health device vendors, personal health compute engine vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE P11073-10415	IEEE Draft Standard - Health Informatics - Personal Health Device Communication - Device Specialization - Weighing Scale	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth weighing scale devices and compute engines (e.g. cell phones, personal computers,	Individuals who use personal health devices in home and mobile environments, personal health device vendors, personal health compute engine vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet

		personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability.	and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE 11073-10417	ISO/IEEE International Standard Health Informatics -- Personal Health Device Communication Part 10417: Device Specialization -- Glucose Meter	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability.	Individuals who use personal health devices in home and mobile environments, personal health device vendors, personal health compute engine vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE 11073-10419	ISO/IEEE International Standard for Health Informatics - Personal Health Device Communication - Part 10419: Device Specialization - Insulin Pump	The scope of this standard is to establish a normative definition of communication between personal telehealth insulin pump devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability.	Individuals who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies (e.g. food and drug administration), telemedicine consultants and businesses.
IEEE 11073-10420	ISO/IEEE International Standard Health informatics -- Personal health device communication	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between	Individuals who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive

	Part 10420: Device specialization -- Body composition analyzer	personal body composition analyzing devices and managers (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability.	data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE 11073-10421	ISO/IEEE International Standard Health informatics--Personal health device communication Part 10421: Device specialization--Peak expiratory flow monitor (peak flow)	The scope of this standard is to establish a normative definition of communication between personal telehealth peak flow monitoring devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability.	Individuals who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies (e.g. food and drug administration), telemedicine consultants and businesses.
IEEE 11073-10424	ISO/IEEE International Standard - Health informatics--Personal health device communication - Part 10424: Device Specialization--Sleep Apnea Breathing Therapy Equipment (SABTE)	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between sleep apnea breathing therapy equipment and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability.	People who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies (e.g. food and drug administration), telemedicine consultants and businesses.
IEEE P11073-10425	ISO/IEEE International Standard Health informatics--	This standard establishes a normative definition of communication between personal health continuous	People who use personal health devices in home and mobile environments, personal health device

	Personal health device communication - Part 10425: Device Specialization--Continuous Glucose Monitor (CGM)	glucose monitor (CGM) devices (agents) and managers ([e.g., cell phones, personal computers (PCs), personal health appliances, set top boxes)] in a manner that enables plug-and-play interoperability.	vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies (e.g. food and drug administration), telemedicine consultants and businesses.
IEEE 11073-10427	ISO/IEEE Standard - Health informatics--Personal health device communication - Part 10427: Device specialization--Power Status Monitor of Personal Health Devices	This standard establishes a normative definition of communication between devices containing a power source (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set-top boxes) in a manner that enables plug-and-play interoperability.	People who use personal health devices in home and mobile environments, personal health device vendors and institutions that receive data from these devices (e.g. hospitals, doctor offices) including several companies that are currently providing patient tracking services and support for these types of patients that are dependent on critical care devices.
IEEE P11073-10428	IEEE Draft Standard Health Informatics - Personal Health Device Communication - Device Specialization - Electronic Stethoscope	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal telehealth electronic stethoscope devices and managers (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability.	People who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE 11073-10441	ISO/IEEE International Standard Health	Within the context of the ISO/IEEE 11073 family of standards for device	People who use personal health devices in home and mobile environments,

	Informatics--Personal health device communication Part 10441: Device specialization--Cardiovascular fitness and activity monitor	communication, this standard establishes a normative definition of the communication between personal cardiovascular fitness and activity monitoring devices and managers (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability.	personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payers (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses
IEEE P11073-10442	IEEE Draft Standard Health informatics - Personal health device communication Part 10442: Device specialization - Strength fitness equipment	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal strength fitness devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability.	People who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payers (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE 11073-10471	ISO/IEEE International Standard Health informatics--Personal health device communication Part 10471: Device specialization--Independent living activity hub	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between independent living activity hubs and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability.	People who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payers (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses

IEEE 11073-10472	ISO/IEEE International Standard Health informatics--Personal health device communication--Part 10472: Device specialization--Medication monitor	Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between medication monitoring devices and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability.	People who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payers (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE P11073-10720	IEEE Draft Standard Module Specifications for a Service-Oriented Medical Device Exchange Architecture	The purpose of this standard is to provide Modular Specifications for point-of-care medical devices. Modular Specifications increase manufacturer-independent interoperability by supporting both developers of standards and products by representing similar device capabilities in a consistent way.	Medical device manufacturers, medical information technology companies, health care providers that use the devices, organizations that utilize these standards (e.g. Integrating the Healthcare Enterprise (IHE)), regulatory authorities, patients.
IEEE 11073-20601	IEEE Draft Standard Health informatics--Personal health device communication - Part 20601: Application profile-Optimized Exchange Protocol	Within the context of the ISO/IEEE 11073 personal health device standard family, this standard defines an optimized exchange protocol and modeling techniques to be used by implementers of personal health devices to create interoperability between device types and vendors.	People who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.
IEEE P2049.1	Standard for Human Augmentation:	This standard is especially needed to divide human augmentation technologies	Device manufacturers, service providers, technology developers, government

	Taxonomy and Definitions	into various subcategories and provide the common language to facilitate discussions and collaborations in the area of human augmentation based on the convergence of nanotechnology, biotechnology, information technology and cognitive science. Within the greater category of human augmentation technologies, different classifications can be made.	agencies, consumers.
IEEE P2049.2	Standard for Human Augmentation: Privacy and Security	This standard is especially needed to define a baseline for human augmentation technologies to preserve the privacy and security of consumers and other people, and facilitate a healthy growth of the industry while minimizing the negative impacts.	Stakeholders include device manufacturers, service providers, technology developers, government agencies, and consumers.
IEEE P2049.3	Standard for Human Augmentation: Identity	This standard is needed to allow users to identify themselves to various services when they are equipped with human augmentation technologies. Getting the user's identity is a common and necessary operation in many services in our daily life, but it could be technically challenged when the user is equipped with human augmentation technologies.	Device manufacturers, service providers, technology developers, government agencies, and consumers.
IEEE P2049.4	Standard for Human Augmentation: Methodologies and	This standard is needed to define a baseline for human augmentation technologies to preserve ethical alignment,	Device manufacturers, service providers, technology developers, government agencies, and consumers.

	Processes for Ethical Considerations	and facilitate a healthy growth of the industry while minimizing the negative impacts.	
IEEE P2788	Standard for Circulating Air Pressure Physiotherapy Equipment Used in the Home Healthcare Environment	No standards currently exist which define a common taxonomy, classification and related parameters for this equipment. These definitions are needed to provide an industry agreed set of definitions to support the needs of manufacturers and regulators, to support protecting consumer's interests and health.	Manufacturers, healthcare providers, regulatory authorities, consumers and other relevant stakeholders
IEEE 1872	Standard for Ontologies for Robotics and Automation	The standard provides a unified way of representing knowledge and provides a common set of terms and definitions, allowing for unambiguous knowledge transfer among any group of humans, robots, and other artificial systems.	Robot manufacturers, system integrators, robot end-users (part manufacturers, automotive industry, construction industry, service and solution providers, etc.), robot equipment suppliers, robot software developers, and researchers/developers.
IEEE P2751	3D Map Data Representation for Robotics and Automation	3D Map Data Representation for Robotics and Automation	Manufacturers, service and solution providers, equipment suppliers in the robotics, automotive, military, and construction industries.