

Industrial and Medical Cyber-Physical Systems: Tackling User Requirements and Challenges in Robotics



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Abstract Robotics is one of the major megatrends unfolding these days. Clearly, robots are capable of doing much more outside the factories than ever imagined, and that has a great impact on the whole society. This chapter provides some practical updates and guidelines on a few exciting aspects of automated technologies: applied robotics in the industry, in service and personal use and in the operating theaters,

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performing not only teleoperated surgeries but complex, delicate procedures as well. However, building reliable autonomous systems is not easy, and for another while, human operators will be required as a fallback option. Ensuring the safety of such hybrid control systems is complex, and requires novel human–machine interfaces. Situation awareness remains a key issue, keeping humans in the loop. Arguably, the social robotic sector is growing much faster than any industrial one, and as predicted, there soon will be robots in every household and around.

1 Introduction

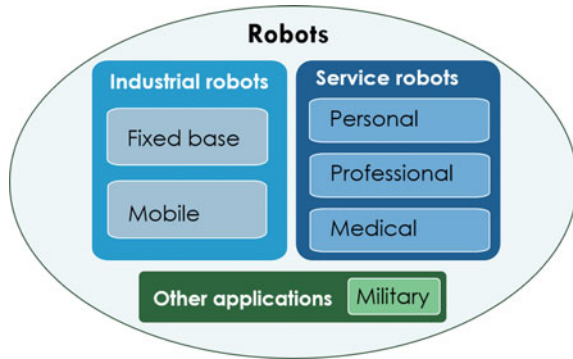
As robotics has been booming for a good ten years now, the complexity of the domain has increased tremendously. Nowadays, real robotic products hit the consumer market on a weekly basis, creating a lot of head ace to the regulatory and standardization bodies, how to keep up with the pace. Nevertheless, the safety requirements regarding critical application in the industry, and especially in the medical domain have not eased, which poses a great challenge for emerging companies and especially startups to comply with. This chapter provides some basic information and practical guidelines regarding the current processes and trends in robot development and manufacturing. Given the various standards and government initiatives affecting the near future of robotics, developers are instructed to always check for the most current requirements when dealing with actual regulatory processes.

Although *Research and Development* (R&D) covers a wide area of robot applications, the traditional robotics market has been manufacturing applications in industrial environments. While a couple of years ago robot system could be classified as manipulators and mobile robots, the exponential boom in robot structures, functions and design means that just the categorization of a particular system poses challenges. This is most critical in the medical domain, where all special safety requirements exist, and it is the manufacturer’s responsibility to meet those, and assess the capabilities and functions of their system properly. A growing number of standards and guidelines deal with the topic, compositing a diverse, sometimes too complex landscape [1].

2 Robot Sectors—User Requirements Perspective

Where it all started, an industrial robot was defined in the International Organization for Standardization’s ISO 8373:2012 as an “*automatically controlled, reprogrammable multipurpose manipulator, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications*”, which definition came under heavy attack for not being inclusive enough (Fig. 1). The new version of the standard (ISO/CD 8373:2019) use the word *robot* in the sense: “*programmed actuated mechanism with a degree of autonomy to perform locomo-*

Fig. 1 Current ISO classification of robots, where the term “robotic system” has been expelled from the standard



tion, manipulation or positioning”. Now the problem is that is incorporates machines with limited functions serving at other industries (like household appliances), while it may not include numerous systems, such as social robots.

Safety has driven manufacturers to keep robots and humans apart by virtual or real cages for many years but this limits human/robot collaboration in the case of the rising domain of service robotics. Moving the core sector away from this central ethos appears to be difficult. Appropriate rules for designing, operating and regulating new service robots need to be developed, where robots and humans can collaborate. Examples are emerging, such as the recent legalisation of driverless cars in the USA (starting in Nevada, California and Florida) [2], the designation of cities in Japan as special zones for robot R&D (e.g., rescue robotics in Fukuoka), and the use of the Dustcart robot for public garbage collection in Peccioli, Italy [3]. Such foreseeable adoption of service robots in public areas is also increasing the likelihood of accidents, potential injuries and damage. As a consequence, litigation fears are escalating for companies developing new types of robots and urgency is growing in having international safety regulations published to allow new service robots to operate in complex real-world, human-occupied scenarios. Naturally, the specific requirements differ in the various domains, and key issues are cited here via industrial, response, personal care and medical robot sectors. These sectors provide a broad basis for understanding key issues, and there is potential for cross-domain robotics research and standards. For example, human–robot interaction, defined as “*information and action exchanges between human and robot to perform a task by means of a user interface*” according to the new ISO 8373, may occur within all of these robotics applications where human safety near industrial robots may have similar challenges and implementations as with personal care robots.

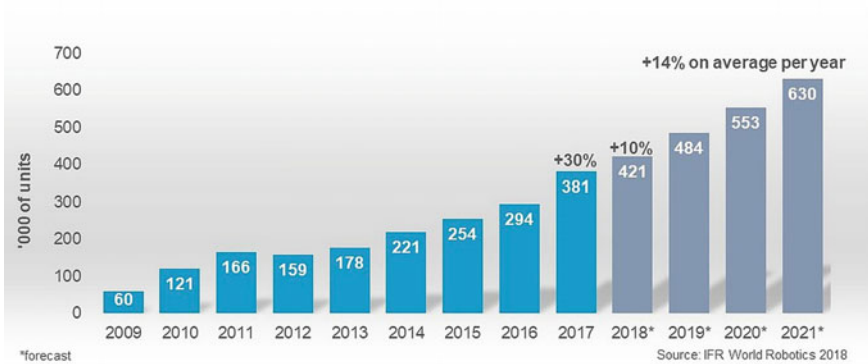


Fig. 2 Estimated annual worldwide supply of industrial robots

2.1 Industrial Robots

Industrial robot arms or manipulators (“*machine in which the mechanism usually consists of a series of segments, jointed or sliding relative to one another, for the purpose of grasping and/or moving objects (pieces or tools) usually in several degrees of freedom*”, as per ISO 8373) are extensively used in manufacturing automobiles and electronics among other industries. Typical classical applications of manipulators include welding, painting, assembly, pick and place (such as packaging and palletizing), product inspection and testing; all accomplished with high endurance, speed and precision. Rapid robot repetitive actions are without variation and with a high degree of accuracy that well overshadows humans. These actions are determined by programmed routines that specify the direction, acceleration, velocity, deceleration, and distance of a series of coordinated motions. Classical industrial robots are fenced and electronically interlocked from humans mandated by safety standards (see below) and by performance standards, such as ISO 9283–1998. Manipulating industrial robots—Performance criteria and related test methods.

The sales of manufacturing robots grows 14% annually according to the in *International Federation of Robotics* (IFR) (Fig. 2). In the past 10 year, the use of robots is shifting from large- to small- and medium-sized enterprises to support one-off product manufacturing [4]. This is largely due to the great success of collaborative robot manipulators (“cobots” in lay media terms) that are considered safe according to the new standards (see below). This domain was pioneered by KUKA (Ausburg, Germany) with their LBR iiwa lightweight manipulator and Rethink Robotics (Boston, MA) with their Baxter collaborative industrial platform. While KUKA celebrated the sales of their 1000th iiwa in 2018, Rethink had to shut down in October 2018, yet the real shooting star of collaborative robotics became Universal Robots (Odense, Denmark), which has sold around 30,000 of their UR manipulators up to date. The US Robotics Roadmap goes on to state that improving manufacturing robotics will:

- retain intellectual property and wealth;
- save companies by making them more competitive;
- provide jobs for maintaining and training robots;
- allow factories to employ human–robot teams that safely leverage each others’ strengths;
- reduce expensive medical problems (e.g., carpal tunnel syndrome, back injuries, etc. and
- reduce time in the pipeline for finished goods, allowing systems to be more responsive to changes in retail demand.

Automated Guided Vehicles (AGVs) are also used extensively in manufacturing mainly for material handling. AGV safety standards (also discussed below) are voluntary in the US and mandated in Europe and Asia. AGV benefits are reduced labor costs and reduced material handling injuries previously caused by manned material handling vehicle driver lack of attention, driver’s driving too fast, or personnel not paying attention. Obstacle detection is therefore a key to allowing AGVs to interact with personnel safely while optimizing vehicle speeds [5]. AGV navigation has advanced using laser guided systems that allow the AGV to determine its position in the plant based on the location of reflectors within the area. The future may be the in-plant equivalent of a Global Positioning System. Obstacle detection systems now use “virtual” (typically laser) bumpers that allow AGV’s to operate at optimum speed.

Mobile manipulators, or robot arms onboard AGVs or mobile bases, (e.g., the KUKA youBot [6]), have been popular with the research stages [7]. This is mainly due to their positioning accuracy and gaps in robot and AGV safety standards when the two are integrated as a mobile robot, and based on the early success, KUKA launched several full-scale industrial mobile manipulators in its product portfolio.

2.2 Response Robots—Rescue Robotics

Disaster management is one of the most serious social issues which involves very large numbers of heterogeneous agents in hostile environments. The international RoboCup—Rescue league (www.robocuprescue.org) and the community involved have been a main catalyst for rescue robotics and work as a standard basis in order to develop practical comprehensive (virtual and real robot) simulators adding necessary disaster modules. The trigger for the RoboCup—Rescue project was the Great Hanshi-Awaji earthquake which hit Kobe City on January 17, 1995 causing more than 6500 casualties, destroying over 80,000 wooden houses, and directly or indirectly affecting more than 1 million people. Damage to all infrastructures was evaluated at more than 1 billion US dollars. RobocupRescue initiatives are divided into two main areas:

- RoboCupRescue Simulation Project: an open resource of research results. This project is itself divided into two main areas, namely the Virtual Robots and the

Agents Simulation projects which target various challenges that exist at the single robot level and the multi-agent system level.

- Real robots: challenges for robots include mechatronics for advanced locomotion, perception and planning, and teleoperation up to full autonomy. Test methods are being developed that measure rescue robot performance based on requirements from rescue responders. The robots are evaluated in special test settings called the NIST Rescue Arenas (robotarenas.nist.gov/competitions.htm). The arenas support the real robot development process with a vision to allow “human rescuers to quickly locate and extract victims” and where “robots are expendable.”

The EUROPEAN ROBOTICS LEAGUE (ERL)—Emergency (<https://www.eurathlon.eu>) is an outdoor robotic competition for cooperative autonomous vehicles from land, sea and air domains. It offers realistic emergency response scenarios, motivated by the aftermath of the 2011 Fukushima Daiichi nuclear disaster. The 2 main tasks for underwater robots are:

- To create a 2D/3D representation of the whole environment, inspect objects, manage leakage of pipes or valves, etc.;
- To find and rescue a missing human in the water.

The involved teams had to collect and analyze data, while fighting against the clock, dealing with various simulated critical hazards [8].

The *Defense Advanced Research Project Agency* (DARPA) began a series of DARPA Robot Challenge (DRC) projects (<https://www.darpa.mil/program/darpa-robotics-challenge>) to further test capabilities of rescue robots, namely humanoid robots to “provide an important baseline on the current state of robotics today and their potential for future use in disaster response.” The DRC aims to advance the current state of the art in the enabling technologies of supervised autonomy in perception and decision-making, mounted and dismounted mobility, dexterity, strength and platform endurance.

2.3 Personal Care Robots

Personal service robots represent one of the fastest growing segment of robotics. There has been dozens of companies established in the past 5–8 years aiming to deliver useful services to the public via robots from waiter robots in busy restaurants to shopkeepers and concierge robots (www.roboticsbusinessreview.com/legal/exclusive_interview_gurvinder_virk_explains_brand_new_iso_13482). Within this category stands personal care robotics. Within ISO Technical Committee (TC) 299 WG 2, there has long been an active work to develop safety standards for personal care robots, defined as “*earthbound robots in direct interaction with the human and contributing directly to their well-being (excluding medical applications)*”. Three general robot types were particularly considered (Fig. 3):

- mobile servant robots;

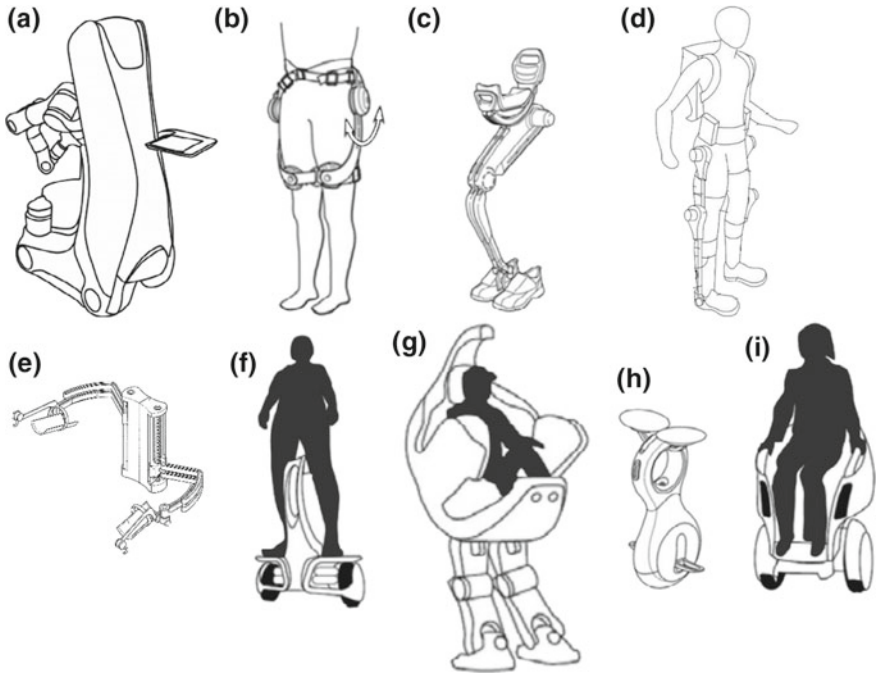


Fig. 3 Types of personal service robots identified in the ISO 13482 standard. **a** Mobile servant robot in domestic environments or public buildings; **b** Leg motion assistive device; **c** Body weight supportive device; **d** Exoskeleton wearable robot; **e** Wearable robot; **f** Carrier with passenger standing on the foothold; **g** Legged passenger carrier; **h** Carrier whose passenger sits on a monocycle; **i** Wheeled passenger carrier

- person carrier robots;
- physical assistant robots.

2.4 Medical Robots

According to current standards and regulations, any system with a medical intended use could be seen as a medical device. In the case of robots, this includes all kinds of systems from psychological rehabilitation to natural orifice surgery [9]. The diversity of functions and appearance make the regulation, standardization of the domain extremely difficult.

For example, autonomous or teleoperated patient visiting robots have been cleared for hospital use in the USA (e.g., the RP-VITA, <https://telepresencerobots.com/robots/intouch-health-rp-vita>), and various minimally invasive and percutaneous systems have been released in Europe (e.g., the iSYS 1, www.interventional-systems.com).

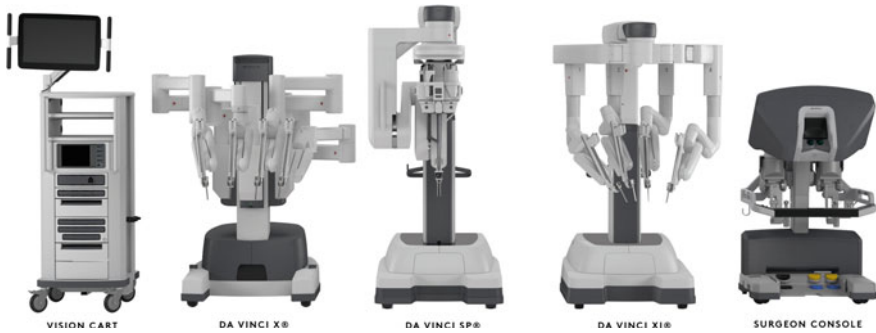


Fig. 4 The currently available da Vinci platforms from Intuitive Surgical: the da Vinci X, Sp and Xi

Surgical robotics and *Computer-Integrated Surgery* (CIS) systems have already seen a rich history of three decades, hundreds of research prototypes and dozens of commercial products, with around 5 million patients treated [10]. The global market for robotic surgery was estimated \$6 bn in 2018. However, much of the recent commercial achievements come from a sole source—Intuitive Surgical’s (Sunnyvale, CA) da Vinci Surgical System—a perfected 20-year-old platform that presents very limited robotic capabilities or autonomous functions (Fig. 4). Despite the tremendous development in medical imaging, image guidance, advanced robot control and human-machine interfacing, the global research community has not managed to create alternatives to the market-leading systems.

CIS systems are strongly application-oriented (ideally driven by a strong clinical need), therefore their entire architecture may be defined by the targeted treatment. It may be extremely hard to switch from one concept to another during a latter development, therefore strategic planning is a must. Different categories of surgical robots have been built for various procedures. Hand-held and directly controlled devices may serve as an incremental upgrade for existing tools, while teleoperated systems represent a whole different field. The advantage of versatility comes with the emergence of issues with control, latency handling and emergency protocols.

Robots can be involved in medical procedures with various level of autonomy [11], and each type requires different approach during system development. This is now recognized by the new International Electrotechnical Commission IEC 60601-4-1:2017 collateral standard (*Medical electrical equipment—Part 4-1: Guidance and interpretation—Medical electrical equipment and medical electrical systems employing a degree of autonomy*), which intends to help a manufacturers through the key decisions and steps to be taken to perform a detailed risk management and usability engineering processes for their medical device with some autonomous functions. Some of the CIS systems serve as a robust tool holding equipment having been directed to the desired position. Systems that are able to perform fully automated procedures—such as CT-based biopsy or cutting—are called autonomous or supervisory controlled devices. On the other hand, if the robot is entirely teleoperated or

remote-controlled (*Robot-Assisted Minimally Invasive Surgery*—RAMIS) the surgeon is absolutely in charge of its motion. The latter consists of three parts:

- one or more slave manipulators,
- a master controller
- a vision system providing visual feedback to the user.

Based on the gathered visual (and sometimes haptic) information, the surgeon guides the arm by moving the controller and closely watching its effect. In most of the cases, the slave system and camera are acting as the remote hands and eyes of the surgeon, and therefore they are key elements of the operation.

Modifying the teleoperation control paradigm, we can introduce cooperative control (also called shared control or hands-on surgery). It means that the surgeon is directly giving the control signals to the machine through e.g., a force sensor [12]. It is possible to read and process these signals in real-time to create the robot's motion. The human is always in contact with the robot, as the master and the slave devices are physically identical. In this case, the robot is the extension of the doctor's hand, equipped with special features and effectors. This approach keeps the human in the loop, and still allows the surgeons to use all their senses. It is often used in the case of micro-manipulation operations, such as micro-vascular, urologic, eye or brain procedures. Cooperative control is a promising way to provide highly integrated robotic support for procedures while applying all the necessary safety standards.

Considering either a less complex needle insertion tool or a teleoperated, Magnetic Resonance compatible robot, prototype development begins with identifying the available technology, and choosing the right architecture. Rigorous approaches to system development earlier discussed (regarding technology, intellectual property, regulations, etc.) are applicable to the medical field as well. However, if it is within the academia, it might fall under the category of fundamental research, driven by scientific goals to innovate new concepts and paradigm to improve future patient treatment. Aiming for new methods, specializing on a certain disease may mean to prototype a proof-of-concept system instead of targeting the achievement of a commercial product. In cutting edge research, it may happen that during the development phase, several new results are achieved that are sometimes transforming the overall outcome of the project, making it necessary to revisit prior decision points. This means higher associated risk, something industrial companies are usually willing to avoid. It often happens that a company licenses one or more patents on prototype systems and then develops its own version, focusing on the actual market needs.

Recently, new trends emerged in the Academic domain to combine efforts regarding hardware and software platform development, while standardization associations also set their focus on the domain [13]. This should allow better cooperation, various groups can build on each other's results rather than competing on the fundamental technology level. Similar initiatives are also pushed by the European Union, where all robotics R&D funds in the next budget cycle (Horizon Europe) are distributed in line with the robotics roadmap forged by the euRobotics aisbl consortium (www.eu-robotics.net). This body acts as a platform uniting Academia and industry, defining fundamental research and application directions.

It is commonly quoted that a medical product needs 10–15 years to grow from the conception of an idea to commercialization. This extremely long time-to-market period requires wise considerations from the developers to ensure the continuous funding of the project. Developing an engineering prototype is only the first step, success in business requires various skills and sometimes entirely different approach towards R&D. The history of the first generation of surgical robots summarized in the next session provides great examples and lessons on the critical aspects of the development process.

As it is understood, besides appropriate manufacturing, adequate control strategies are required to ensure maximal effectiveness and safety. Currently leading teleoperated and hands-on systems have to solve major issues with system accuracy, force feedback and communication latency. Automated surgery is a technologically challenging area; it needs fine adaptation to the changing environment of the operating room.

3 Robot Standards Development

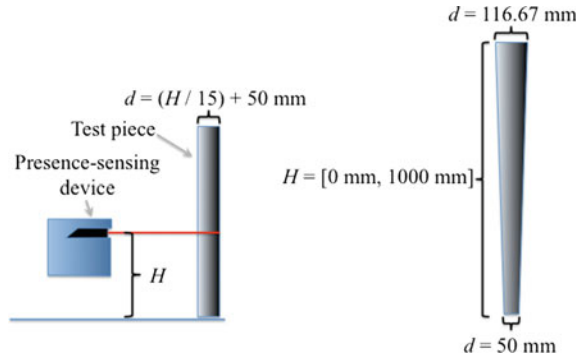
3.1 Industrial Robot Standards

Within the international Standard Development Organizations (SDOs), the main efforts for industrial robots are done in ISO TC299/SC2/WG3 Industrial robot safety. ISO provides guidelines for the safety of industrial robots in the two parts of ISO 10218 (*ISO 10218-1:2011 Robots and robotic devices—Safety requirements—Part 1: Robots, 2011 and ISO 10218-2:2011 Robots and robotic devices—Safety requirements—Part 2: Industrial robot systems and integration, 2011*). ISO 10218-1 outlines the requirements for the construction and control of the robots, and includes provisions for connections, axis limiting, actuation, etc. In contrast, ISO 10218-2 establishes the safety requirements for integrated robot systems, including safeguards and the integration of multiple robots and tools. Together, they ensure the safety for the entire robot workcell. *American National Standards Institute* (ANSI) and the *Robotics Industries Association* (RIA) adopted both parts of ISO 10218 in 2012 for the joint ANSI/RIA R15.06 Industrial robots and robot systems—Safety requirements U.S. standard for robot safety. We refer to the two parts of ISO 10218 collectively as the industrial robot safety standards for simplicity.

Artifacts for the functional validation of presence-sensing for industrial robots are based on the mandated vertical and horizontal detection capability of the protective sensors, given in ISO 13855 (*Safety of machinery—Positioning of safeguards with respect to the approach speeds of parts of the human body, 2002*). This detection capability, d , is defined as:

$$d = (H/15) + 50 \text{ mm}, \quad (1)$$

Fig. 5 Current test pieces used by industrial robot standards. The range of artifact radii is a function of the detection zone height



where $H = [0 \text{ mm}, 1000 \text{ mm}]$ is the height of the detection zone. The artifact is a cylinder of variable diameter based on the height of the detection zone (Fig. 5), and is representative of a human arm or leg.

Historically, the safety of humans working close to robot systems was maintained by the strict separation of man and machine by physical safeguards. However, the 2011 revision of ISO 10218 added language that supports limited human-robot collaboration. The new wording enables the physical interaction between humans and robots per the guidelines of ISO Technical Specification (TS) 15066 (*ISO/TS 15066:2016. Robots and robotic devices—Industrial safety requirements—Collaborative industrial robots*). The U.S. National Institute of Standards and Technology (NIST) was helping to draft ISO TS 15066, and is currently developing evaluation methods and metrics for the provisions of maintaining safe speeds and separation distances (“speed and separation monitoring,” SSM) of the robot while humans are nearby [14], and of reducing the potential for injury by limiting the transfer of forces and pressures from robots to humans (“power and force limiting” PFL) in the possible event of collisions [15].

Automated guided vehicles (AGVs) are also prevalent in industrial manufacturing and distribution facilities. ANSI/Industrial Truck Standards Development Foundation (ANSI/ITSDF) B56.5 standard for AGVs is the US safety standard for AGVs (*ANSI/ITSDF B56.5. Safety Standard for Driverless, Automatic Guided Industrial Vehicles and Automated Functions of Manned Industrial Vehicles, 2012*). ANSI/ITSDF B56.5 specifies the safety requirements for the design and use of AGVs and automated functions of manned industrial vehicles. In Europe, the AGV must comply with the *Machinery Directive 98/37/EC* [16], among other emission and power standards. There is also a European standard that is normally used, EN1525 (*Safety of industrial trucks—Driverless trucks and their systems, 1998*), which is a harmonized standard used to conform to the safety requirement of the Machinery Directive. Attempting to further harmonize safety standards, the ISO 3691-4.2:2016 (*Industrial trucks—Safety requirements and verification—Part 3: Additional requirements for trucks with elevating operator position and trucks specifically designed to travel with elevated loads*) was developed over many years. By the

time it was released, AGV technology state-of-the-art surpassed the technical content standard. Similar to robot standards, AGV standards use artifacts that represent the lower portion of a human leg, the profile of a person lying down, and a flat plate made of highly reflective materials in a manufacturing environment.

The next generation of AGV safety standards expected to include criteria for:

- measurement of dynamic obstacles and obstacles appearing in the “Exception” or stop zone;
- three dimensional (3D) imaging from an AGV to detect overhanging obstacles;
- manned vehicles with automated functions when operators cannot see pedestrians;
- detection of humans (in line-of-sight or occluded) and located near AGVs [17];
- robot arms onboard AGVs. A new AGV performance standard is also proposed to standards bodies to provide AGV users and vendors test methods for AGV applications. The performance standards may also cover robot arms onboard AGVs.

3.2 IEEE RAS Standards

The *Institute of Electrical and Electronics Engineers (IEEE) Robotics and Automation Society (RAS)* has been active in standardization for quite a while, helping to explain the state-of-the-art in this technological domain—rather than predicting that. The first-ever RAS standard: *Ontologies for Robotics and Automation IEEE 1872–2015* (<https://standards.ieee.org/develop/wg/ORA.html>) is focusing on the general ontological framework of the field, which is now followed by more detailed, domain specific standards. A notable example for that is the P1872.2 Standard for *Autonomous Robotics (AuR) Ontology* committee’s work. Defining task and task execution for robots is now being developed under the P1872.1 Robot Task Representation. “The standard provides a unified way of representing robot task knowledge and provides a common set of terms and definitions structured in a logical theory, allowing for unambiguous knowledge transfer among groups of human, robots, and other artificial systems. It will link the existent core ontology to the draft/future sub-ontologies. The proper definition and implementation of tasks and task-based robot control has become a key toward advanced human-robot interaction. A common robot task representation will also allow for greater reuse of task knowledge among research and development efforts in the same robot domain (e.g., within industrial robotics) as well as efforts in different robot domains (e.g. between industrial robotics and service robotics).” The first draft is expected by the end of the year.

3.3 *Response Robot Standards*

ASTM search and rescue operations standards cover the personnel, equipment, and procedures relevant in the performance of *Search and Rescue* (SAR) operations. Several ASTM international emergency response robot standards have recently been developed and adopted or are in the standards development process. Response robots are a broad category that include applications such as urban SAR, bomb-disposal, law enforcement, and other similar types of deployments.

ASTM and NIST are developing a comprehensive set of standard test methods and associated performance metrics (e.g., E54.08 and ASTM E2566-08) to quantify key capabilities of emergency response robots. These test methods address responder-defined requirements for robot mobility, manipulation, sensors, energy, communications, human-robot interfaces, logistics and safety for remotely operated ground vehicles, aquatic vehicles, and micro/mini aerial vehicles (under 2 kg) for urban environments. The goal is to facilitate emergency responder comparisons of different robot models based on statistically significant robot performance data, captured within the standard test methods, to help guide purchasing decisions and understand deployment capabilities. The test methods also support operator proficiency training and foster development and hardening of advanced mobile robot capabilities. The process used to develop these test methods relies heavily on international robot competitions to refine proposed test apparatuses and response robot evaluation exercises in responder training facilities to validate the test methods [18].

The suite of standards being produced by ASTM International Subcommittee E54.08 on Operational Equipment, have main headings: “ASTM Standard Test Methods for Evaluating Emergency Response Robot Capabilities,” followed by specifics, for example, for robot mobility and manipulation. ASTM E2566-08 addresses the human operator combined with the robot as a test method for visual acuity of on-board robot video systems for robot teleoperation for SAR applications.

3.4 *Personal Care Robots Standards*

The ISO TC299 WG4 work culminated in three new documents:

- *ISO 13482—Robots and robotic devices—Safety requirements for personal care robots* (published in 2014)
- *ISO/DTR 23482-1—Technical report: Validation criteria for personal care robots*
- *ISO/PRF TR 23482-2—Application guide for ISO 13482, Part 2: Application Guide* (to be published as a technical report as well).

With respect to the special situation that personal care robots act in direct vicinity of the user, and that the autonomy of these robots is generally high, some clauses were added to the above documents, that are unique in machinery safety, such as instructions dealing with incorrect autonomous actions and decisions, hoping these will help the manufacturers when clearing their systems [1].

3.5 Medical Robot Standards

Clearance applications (and the following continuous communication with the regulatory bodies) include discussion of electronics design, imaging systems' performance, embedded software analysis and clinical trial design and patient outcome validation. The procedures both in Europe and in the U.S. are focusing on the safety and transparency of systems [19].

For CIS systems, the *ISO 13485:2003 Medical devices—Quality management systems—Requirements for regulatory purposes* is in effect. It is possible for ISO 9001 and 13485 compliant companies to self-certify (CE mark) their products within certain limitations, and the Brussels-appointed *Notified Body* would periodically audit them. From May 2020, a new European *Medical Device Regulation* (MDR) is coming into effect, with much stricter processes for validation and post-market surveillance (ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en).

International bodies are exerting great effort to standardize medical robotics similarly to industrial robotics. However, there are no widely accepted regulations. Some of the existing robotic and medical device development standards are applicable to CIS currently. In 2004, ASTM initiated a new standards committee (ASTM F04.05) under the title *Standard Practice for Measurement of Positional Accuracy of Computer Assisted Orthopaedic Surgical Systems* (CAOS). The goal was to develop an international standard for metrology, validation and performance of CAOS systems [20]. The first draft (from 2007) deals with the localizer functions of navigation systems (optical, mechanical or electromagnetic). The defined generic measurement board—nicknamed Nebraska phantom—was machined from aluminum-alloy, and was tested with three different CIS systems [21]. It is a multi-surface object with 47 identical fiducial points (0.75 mm deep cone-shape holes) distributed on its surface.

Supporting the ASTM group, a multi-institution technical committee presented a white paper, calling for standardization in many areas of CIS [22]. Based on technological and economic analysis, metrology and standards should be applied especially to the following categories of medical devices:

- computer-assisted navigation and surgery,
- surgical robots (mostly in manual control mode),
- surgical robots and phantom (artifact) devices,
- stimulation devices,
- drug-delivery and physiologic monitoring devices.

The *ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems* was released in 2010.

Another clinical phantom (the *Computer-Assisted Orthopaedic Hip Surgery—CAOHS Artifact*) was built at NIST to quantify task specific measurement uncertainty. It was designed to mimic hip joint using magnetic ball-and-socket to be able to simulate hip replacement procedures

Telesurgery require additional regulations. An earlier report [23] discussed the technical and human issues based on the existing standards according to

1993/42/EEC, *Medical Devices Directive* (MDD) and the third edition of the IEC 60601-1 (2006) for tele-neurology.

In the past eight years, a joint ISO/IEC JWG (IEC TC 62/SC 62D) forged a new ISO/IEC joint Technical Report (TR) on the problem of autonomy for medical electrical systems (MES), including robots (IEC/TR 60601-4-1). This is a first step towards the standardized assessment of robot capabilities, primarily focusing on their autonomous functions, while practical guidelines on methods for robot categorization and certification are also on the horizon. The new TR offers an unambiguous solution to describe and assess the autonomous capabilities of an MES via the concept of *Degree of Autonomy* (DoA), a term that was not defined in the ISO 8373:2012. Relying on some earlier work in the field of industrial automation and service robotics [24], the TR recommends the parametrization of DoA along four cognition-related functions of a system, which are affecting capabilities of an MES to Generate, Execute, Monitor and Select an option related to a robot task. Each of these functions can be driven by a human or a computed (or mixed under some conditions), which would then lead to the objective assessment of the DoA of the full system. DoA can vary from low to high, with zero meaning “no autonomy”, and the other end of the scale meaning a “full autonomy” system. DoA can be classified at different granularity levels, depending on where and how the above safety functions are implemented. Next, basic safety and essential performance standards were created by the same JWG, resulting in a brand new standard to be published later this year (*IEC/CD 80601-2-77: Medical electrical equipment—Part 2-77: Particular requirements for the basic safety and essential performance of medical robots for surgery, 2019*). It defines the basic types of surgical robots and tools, and identifies integrated components. The standard collects all relevant mechanical and thermal hazards, along with the fault conditions of the equipment and the required usability trials.

The same work has been done for rehabilitation robots in parallel, and another particular standard coming from the same JWG to address the hazards associated with the loss of Situation Awareness (SA) in rehabilitation robotics (*IEC/CD 80601-2-78: Medical electrical equipment—Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, compensation or alleviation of disease, injury or disability, 2019*). This may be critical when a human operator is needed to supervise a task, or interact with a robot to reduce risk. According to the new standard, the manufacturers will have to include fundamental information about the testing and SA for their upcoming robotic systems.

4 Standards Considerations—Challenges

4.1 Safety Metrics

There exist published methodologies to support the safety of design and development of robotic devices. Their goal is to reduce errors that can be either systematic (a series

of errors resulting in an adverse event) or specific (the event itself is a form of error). A widely employed method is the *Hazard Identification and Safety Insurance Control* (HISIC) policy, that has been applied to multiple robotic systems so far [25]. HISIC breaks down the issue into seven principles:

- definitions and requirements;
- hazard identification;
- safety insurance control;
- safety critical limits;
- monitoring and control;
- verification and validation;
- system log and documentation.

Further, particularly for the critical application of medical robots, a Computational Evolution method [26] and a *Unified Modeling Language* (UML) based approach have been successfully prototyped [27], relying on safe design, safe execution and risk assessment as cornerstones. Risk management in general is a key component of the entire medical/electrical device safety:

- risk analysis (including system definition, hazard identification and risk estimation);
- risk evaluation (determine risk tolerance levels);
- risk control (implementing the right action for maximum safety).

4.2 Performance Metrics

A major step in the evaluation of a robotic device is system-level performance assessment, especially in terms of spatial accuracy and safety. Thorough tests are required, as the overall precision may be the highly non-linear function of the intrinsic and registration accuracies.

Precision of robotic systems can be represented by the accuracy and repeatability of the device to characterize the overall effect of the encoders' fineness, rigidity of the structure and the compliance of the hardware elements (the servo motors, the gears or the links). Both terms are defined for industrial robots in the ISO 9283 (prepared by the former *ISO TC-184/SC2 Robots and Robotic Devices*), where accuracy refers to a robot's ability to position its end at a desired target point within the working volume. The absolute positioning accuracy shows the error of the robot when moved to a prescribed joint angle or Cartesian position. This expresses the mean difference between the actual pose (position and orientation) and the pose calculated from the mathematical model of the robot. "Repeatability is the ability of the robot to reposition itself to a position to which it was previously commanded or trained", as defined in [28]. It is the standard deviation of the positioning error acquired through multiple trials to reach the same joint values. Repeatability is typically smaller for

manipulators than accuracy, while both numbers are largely dependent on speed, payload and the range of motion [20].

There are three different types of accuracies (in terms of spatial errors) that can be specified with different error numbers (determined in general) according to [29, 30]:

- intrinsic (technical) accuracy (with typical range of 0.1–0.6 mm);
- registration accuracy (0.2–3 mm);
- application accuracy (0.6–10 mm).

Intrinsic accuracy applies to certain elements, such as the robot or the navigation system. It describes the average error of the given component in operational use. Random errors (e.g., mechanical compliance, friction, loose hardware), resolution of the imaging device, inadequate control and noise can all result in low intrinsic accuracy. On the user interface side, discretized input and modeling errors may further decrease precision.

Registration errors are also present, as computational methods involve some kind of residual errors. It is only possible to find a normalized (e.g., least squares optimized) solution for a mathematical fitting problem

4.3 *Boundary Issues*

Emerging applications in medical and personal care robotics have to consider close human–robot interaction as well as human–robot contact situations because these are essential for effective and safe operations. The development and adoption of international safety standards are one of the best ways in which new products can be rapidly commercialized.

The intended use of the robot as specified by the manufacturer is the key issue whether it is considered to be a machine or a medical device. However, manufacturers must also take reasonable measures against “foreseeable misuse” which can easily happen in many systems close to the medical/non-medical boundary [9]. Hence, if a manufacturer defines its robot as a machine but it is clear that someone could also use it as a medical device, any additional risks must also be mitigated adequately. In this way, manufacturers need to think about the consequences of introducing a new service robot product into the medical/non-medical environments. It is likely that new service robots close to the medical/non-medical boundary may need both medical and non-medical risk assessments to be carried out to ensure all possibilities will be adequately covered; this may lead to other difficulties and that the final products may become too expensive and unaffordable. This would be a tragedy and all efforts need to be taken to facilitate the development of the new service products as they have a vital role to play in modern and future society. Importantly the decision and the proper execution of the assessment lies with the manufacturer of the robot product, be a university spin off or a multinational company but society must assist them

to bring the new products to the market place in an acceptable manner so that all concerns and stakeholders viewpoints have been taken into consideration.

4.4 Financial Interests and Applicability of Safety Standards

Service robots are strongly application-oriented, and so their entire architecture may be defined by the target domain. The emergence of companies focusing on the full spectrum of design, development, manufacturing and sales has created a practice of profit-oriented design, which raises ethical questions when assessment is undertaken, e.g., a surgical system applied as a life saving device.

Intuitive Surgical Inc. leads the market with their surgical system having been commercialised using the “razor and razor blade” model; they profit from robot sales, service contracts and also from selling many laparoscopic tools, since those are sterilisable only 8–12 times. This means that hospitals buying the da Vinci system need to perform more surgeries to pay for it, while it generates further purchases of its supporting tools [19]. This has also induced the morally questionable phenomenon that buying a da Vinci robot increases the number of prostatectomy procedures performed locally [31].

4.5 Liability

The concepts of acceptable risk and risk-benefit analysis (well established in industrial robotics) might be immoral in personal care or medical robot sectors. The concept of “acceptable risk” is also extremely hard to be introduced into an emotional context (e.g., medical applications), where relatives and friends would always assess and deal with hazards fundamentally differently. It is critical to investigate and define a priori, who will be liable if things go out-of-control, or become too confusing for the medical staff and other users (including patients and citizens) to follow the original protocol of use. The relevant new standards must incorporate these human factors to ensure wide acceptance. In the meantime, manufacturers and governments should look into the statistics, and adjust local policies for different service robots in use. This is important, since a large number of deployed robots also means that there is an exponential rise in the number of hazardous incidents [32].

The role of the regulatory bodies is not clarified entirely either: while there are 3–4000 independent 510(k) submissions annually, only 30–50 PMA arrive to the *U.S. Food and Drug Administration* (FDA). The basic idea behind these regulations is to prevent failures and safety issues originating from bad design, yet the abuse of the 510(k) pathway made FDA to reconsider many aspects of its validation procedure, since clinical use and patient outcome was not even to be verified during the validation [33]. At the most, the system should show the capability to perform a procedure with the same effectiveness as an existing (manual) technique. FDA can

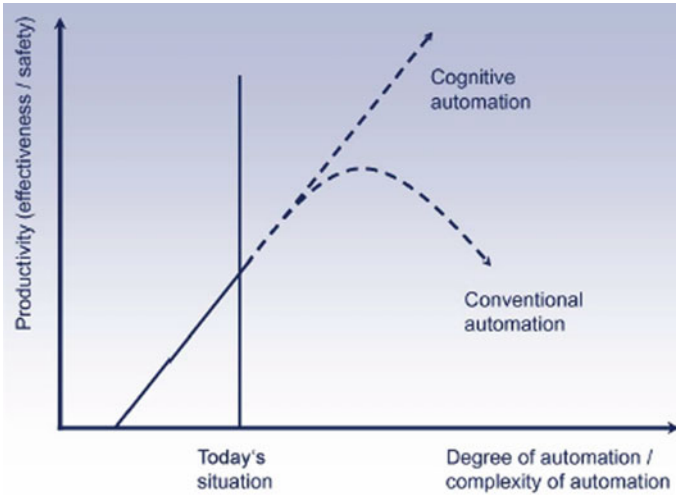


Fig. 6 Graph showing the need for more intelligent automation to improve productivity [34]

be argued that is used to rely on the selectivity of the market, which should only allow for the existence of well-sustained systems with significant added value to the surgical procedure. In the meanwhile, from 2018 on, for low risk medical devices, FDA offers an expedited 510(k) pathway (www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626838.htm).

5 Next Generation of Robots

With respect to manufacturing, high reactivity, agility and adaptability “is required of modern production systems and can only be reached by human operators with their immense cognitive capabilities allowing them to react to unpredictable situations, to plan their further actions, to learn and to gain experience, and to communicate with others.” [34] New concepts are therefore required that apply these cognitive principles to the planning processes and control systems. Figure 6 shows that increasing automation without cognitive ability will eventually decrease production.

The 2013 U.S. Robotics Roadmap [4] and its European counterpart (<http://www.eu-robotics.net/downloads>) were developed with key researchers expressing future expectations for not only manufacturing, but also healthcare, service, space, and defense robotics. The Roadmaps discuss that today’s manufacturing is “a patchwork of ad hoc solutions” and the “the next generation of miniaturized, complex products with short life cycles requires assembly adaptability, precision, and reliability beyond the skills of human workers.” Assembly-line robots working side-by-side with human workers is expected for one-of-a-kind, discrete part manufacturing and

assembly with dexterous manipulation with highly complex hands “using tactile-arrays approaching human hands.” Additionally, autonomous navigation is expected in any environment that humans can drive with perception for unstructured environments [35]. Although manufacturing based, cross-over to medical and personal care robotics is expected using nano-manufacturing of nano-robots for drug delivery, therapeutics and diagnostics. Key points for the future of robotics are: adaptability, learning, advanced control and planning, human-robot collaboration, high performance and high dexterity, with an overarching issue of safety [36].

5.1 Standards Needed to Bridge the Gap

Current standards show, for example, adding a robot arm onto a mobile base, uncovers gaps in the ANSI/ITSDF B56.5 AGV safety and ISO 10218 robot safety standards do not completely account for a mobile robot [37]. Both standards provide language to minimize the risks associated with the unexpected enabling of AGV and robot drive motors and for handling the presence of people/objects within the robot’s work volume and AGV’s path. However, in many cases, the risks associated with the operational conditions are specific to either the robot arm or the AGV base. For example, conflicting emergency stop commands from either the robot or AGV is only covered within the AGV safety standard. As such, directly addressing mobile robot risks will be required and the risk mitigation must be added to either the AGV or robot standard or begin a new standard to address the gaps between them.

ASTM International has been the main standards development organization for rescue robots, establishing the E54.08 rescue robot standards thrust. First responders, robot developers, and others use a standard development process as shown in Fig. 7, where requirements, performance evaluation, and validation are applied prior to robot deployment. The process uncovers gaps in current standards or needed standards that are not yet developed [38]. Every standard should be periodically reassessed and maintained, as per the founding principle of the SDOs [39].

Two years ago, ISO created a Study Group (SG) focusing particularly on the gaps and structural issues in existing robotics standards (*ISO/TC 299/SG1—Gaps and Structure*). Their aim is to identify missing components and overlaps to make ISO standards more consistent.

IEEE RAS has also initiated a joint forum for SDOs involved in robotics standards to work on the harmonization of key aspects of the domain. As a first step, the assessment of the complete standards landscape was done (<http://robotistry.org/standards/StandardsList.html>).

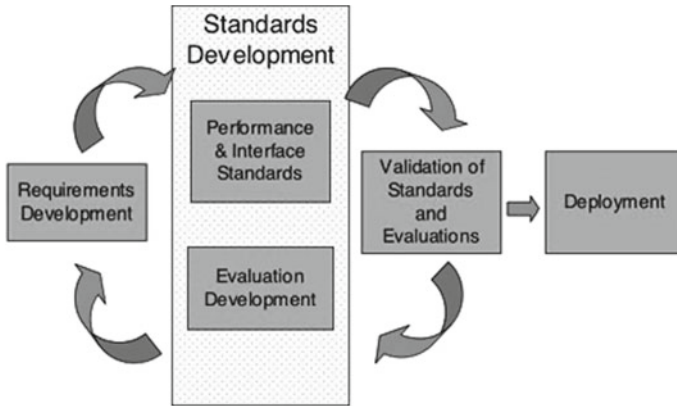


Fig. 7 Robot standards development process and life cycle [38]

6 Societal Impact of Standards

Human medicine has changed a lot recently due to ICT, with much bias against robotic systems. Elevating it to the regulatory level, the EU is working on a robot ethics doctrine [40]. While standards are to be followed by the industry, through the products cleared, they impact the entire society. Recognizing this fact, multiple SDOs started to work on ethical standards recently, including the ad hoc group (AHG) *ISO AHG 79, Autonomous Systems—Ethics*, and also, the IEEE is drafting relevant standards. Recognizing the great responsibility to guide and direct the public through the rough waters of modern technology, IEEE launched the Global Initiative on Ethics of Autonomous and Intelligent Systems (“The IEEE Global Initiative”, <https://ethicsinaction.ieee.org/>) with the mission “To ensure every stakeholder involved in the design and development of autonomous and intelligent systems is educated, trained, and empowered to prioritize ethical considerations so that these technologies are advanced for the benefit of humanity.”

A series of ethical standard working groups were initiated, to establish guidelines for system developers, once we cannot predict the direct outcome of these R&D processes. This was a forward looking, bold step, and the first tangible outcome is the *Ethically Aligned Design: A Vision for Prioritizing Human Well-being with Autonomous and Intelligent Systems* technical report (edition 2, December 2017) (http://standards.ieee.org/develop/indconn/ec/autonomous_systems.html) with the aim to advance a public discussion on these topics, to facilitate the emergence of national and global policies, and to inspire the creation of the P7000 standard family: most notably, the *IEEE P7000—Model Process for Addressing Ethical Concerns During System Design*, *IEEE P7001—Transparency of Autonomous Systems* and *IEEE P7007—Ontological Standard for Ethically Driven Robotics and Automation Systems*.

There is a fierce debate ongoing in the public about the robots taking away people's jobs [41]. While this topic is out of the scope of this chapter, the public opinion is definitely putting a pressure on SDOs to facilitate the adaption of safe robot application for the benefit of all.

From this chapter, military applications are omitted, while they also have a huge impact on the overall technology development and may influence the whole society. There has been a lot of public arguments about the development and use of automated weapons, with far from any conclusions or international consensus (spectrum.ieee.org/automaton/robotics/military-robots/army-considers-replacing-thousands-of-soldiers-with-robots).

7 Conclusions

We are witnessing the rise of the next generation robots for manufacturing, health-care and service with respect to personal care, medical, industrial, and rescue robots. These shall be accompanied by new standards that address robot mobility, sensing, navigation, planning, integration into operational caches, and human system interaction. Safety standards for industrial robot arms and automated guided vehicles are already being written to reduce the risk to humans in industrial environments, but only with regard to their respective platforms. While there exists some overlap and complementing protective clauses, neither the industrial robot safety standards nor the new safety standards fully address all of the potential hazards of e.g., mobile manipulators or image-guided medical robots, when applied either separately or collectively with other systems (cameras, navigation, etc.). Existing protections break down further when robotic systems are introduced into a manufacturing environment or operating room free of physical barriers between robots and humans.

Some argue that while existing standards are mostly aimed at machinery, they are regularly employed for medical devices as well, and applied to personal care robots sought to improve the quality of life of humans. Roboticists and other stakeholders have the responsibility to properly employ the standards, and do not abuse the existing regulatory pathways' shortcomings. They shall be thoughtful of the roles that service robots will play, the kind of support the care robots should or should not provide, and the impact that robot care will have on their layman users. For personal care robots, the safety requirements are already given based on machine safety guidelines, whereas medical robots' standardization guidelines need basic safety and essential performance requirements to be published and practiced. The key issues is that some analysis of risk–benefit posed to the patient needs to be carried out in the medical applications, especially with invasive systems (surgical robots, that may be a major factor of risk.

It is foreseen that more autonomy will soon be introduced with personal care and medical robots, offering more assistance to lay persons, with new rising hazards originating from the routine interaction. From the user's (and the manufacturer's)

point of view, safety is the single most important feature of any robotic device working together or directly in contact with humans.

Compliance with international guidelines and standards will remain a pre-requisite of entering foreign markets. Standards present real value only if they are widely accepted and followed, therefore SDOs need to focus on the applicability of the new standards, especially when they emerge to be regulations to be followed. The community strongly believes that future standards should focus more on practical applied safety and system level improvement, rather than pure technical metrics. Working groups will continue to labour towards that goal.

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