1. Introduction

There have been significant advances in industrial, service, and medical robotic technologies over recent years and many impressive systems have been developed. Examples include\(^2\): Rethink’s Baxter\(^1\), Honda’s Asimo\(^4\), iRobot’s
Roomba\textsuperscript{5}, and Intuitive Surgical’s da Vinci Surgical System\textsuperscript{6}. The current robot market is estimated at $45B/year (made up of $25B for industrial robots and $20B for service robots) and is expected to increase to $79B by 2017 ($32B and $46B, respectively)\textsuperscript{7}. Despite the many successful installations at industrial sites, robotics has not yet matured sufficiently to expand from its traditional roots to meet the global challenges of the rising service domain. Reasons include:

- the lack of International Organization for Standardization (ISO) safety requirements for close robot–human interaction;
- ISO 13482\textsuperscript{8} will be the first ISO robot safety standard allowing robot-human contact; however, it will not be widely clear to manufacturers how the safety requirements should be realised;
- difficulty of integrating new technologies into existing systems leading to considerable waste of effort due to reinventing-the-wheel scenarios;
- lack of effective coordination of results that leads to many labs doing the same work because normative knowledge for robotics is missing.

This lack of knowledge and experience must be addressed collectively by stakeholders worldwide and steps to encourage open collaboration between robot research and robot standardization communities made so that globally acceptable guidelines for robot safety, benchmarking, and performance testing are reached to spur rapid technical and commercialisation development. This can only be achieved through harmonisation between researchers, and standardisation and regulatory bodies as discussed in this paper.

2. Robot sectors

Although research and development (R&D) covers a wide area of robot applications, the traditional robotics market has been manufacturing applications in industrial environments. An industrial robot is defined in ISO 8373 as an “\textit{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}”. Safety has driven manufacturers to keep robots and humans apart by virtual or real cages for many years but this limits human/robot collaboration. However, moving the core sector 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 (e.g., Nevada, California, and Florida), the designation of cities in Japan as special zones for robot R&D (e.g.,

\textsuperscript{5} \url{www.irobot.com/us/learn/home/roomba.aspx}
\textsuperscript{6} \url{www.intuitivesurgical.com/}
\textsuperscript{7} \url{www.marketandmarkets.com}
\textsuperscript{8} ISO/FDIS 13482:2013 Robots and robotic devices – Safety requirements for personal care robots.
Fukuoka), and the use of the Dustcart robot for public garbage collection in Peccioli, Italy. 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, personal care and medical robot sectors.

3. **Robot standard development**

Standards provide crucial communication, alignment, and compatibility at an international, national, industry, and individual organization level. Standards help make technologies accessible to all by harmonizing language, state-of-the-art knowledge, management, and industry best practices, which are all requirements in a highly regulated environment.

Although there are many organisations involved in international standardization activities, Digital Imaging and Communications in Medicine (DICOM)\(^9\), Institute of Electrical and Electronics Engineers Standards Association (IEEE SA)\(^10\), Object Management Group (OMG)\(^11\), Association of Computing Machinery (ACM) as well as national/regional efforts American Society of Mechanical Engineers (ASME)\(^12\), National Institute of Standards and Technology (NIST)\(^13\) and Comité Européen de Normalisation (CEN)\(^14\), Association for Computing Machinery (ACM)\(^15\), a non-standards body, with the two main standards bodies being the International Organization for Standardization (ISO, www.iso.org), and International Electrotechnical Commission (IEC, www.iec.ch) who have been responsible for the majority of the international robot standards that are in current use.

3.1. **Industrial robots**

The main international standardization efforts for industrial robots are in ISO TC184/SC2/WG3 Industrial robot safety. WG3 has recently updated the safety requirements for industrial robots\(^16\) by allowing limited collaborative modes within ISO 10218-1, -2. The intention is to develop a Technical Specification to

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\(^9\) DICOM: Digital Imaging and Communications in Medicine, www.dicom.com
\(^10\) IEEE Standards Association, standards.ieee.org
\(^12\) ASME: American Society of Mechanical Engineers Standards, www.asme.org/kb/standards
\(^13\) NIST: NIST standards, www.nist.gov/srm
\(^14\) CEN: European standards, www.cen.eu
\(^15\) ACM. Advancing Computing as a Science & Profession, www.acm.org
enhance the collaborative operation (ISO/Technical Specification (TS) 15066) by allowing closer human–robot interaction\textsuperscript{17, 18}.

Other planned activities include addressing industrial robot and automated guided vehicle (AGV) standards. The National Institute of Standards and Technology (NIST)’s Next Generation Robotics and Automation Program (NGRA)\textsuperscript{19} includes several projects to support these efforts with the objective “to develop and deploy advances in measurement science to safely increase the versatility, autonomy and rapid re-tasking of intelligent robots and automation technologies for smart manufacturing and cyber–physical systems applications.”

Industry is interested in leveraging the dexterity and versatility of people and the precision and repeatability of robots by enabling collaboration in dynamic and reconfigurable manufacturing environments. Such collaborations, however, are not possible today. According to current standards, industrial robots are still not capable of safely interacting with their human co-workers in highly variable task scenarios. Today, low power, low capacity robots are being developed for human–robot collaborative activities in manufacturing. Generic example activities might include tasks that are repetitive, such as assembly line support; parts pick-and-placement; insertion of small, lightweight items in boxes for shipment, and assembly of simple, easy to grasp parts without force-controlled connections. These robots may not currently hold the same accuracy and repeatability as traditional robots used for automobile and aircraft manufacturing. Current ISO standards allow some human–robot collaboration (e.g., speed and separation monitoring) for industrial robots \textsuperscript{[1]}.

Mobile equipment is extensively used in manufacturing and there is a growing acceptance of either partially or fully autonomous equipment in the field. A major problem, however, is that (especially small) manufacturing facilities frequently operate with people and mobile equipment moving through the same cluttered, constantly-changing environment. Safety is of paramount concern, and standards are essential to reduce the potential injury. The NIST Mobile Autonomous Vehicle Obstacle Detection/Avoidance Project develops standard test methods and performance measures for semi-autonomous and autonomous industrial vehicles that use advanced sensor and control systems and operator alerts to help improve standards. For example, this project performs measurements using AGV safety sensors and advanced three dimensional, non-contact sensors on standard-sized test pieces—similar to human leg and body profiles—for the ANSI/ITSDF\textsuperscript{20} B56.5 AGV safety standard \textsuperscript{[2]}.

\textsuperscript{17} HSE Research Report RR906, Collision and injury criteria when working with collaborative robots, UK, 2012.
\textsuperscript{18} BG/BGIA U 001/1009e Report, Risk assessment according to machinery directive: design of workplaces with collaborative robots, Germany, 2009
\textsuperscript{19} http://www.nist.gov/el/isd/ps/nextgenrobauto.cfm
\textsuperscript{20} Industrial Truck Standards Development Foundation website, www.itsdf.org.
3.2. **Personal care robots**

ISO TC184/SC2/WG7 Personal care robot safety has been developing the ISO 13482 safety standard for personal care robots comprising mobile servant, physical assistant, and person carrier robots. The standard, to be published in August 2013, defines the safety requirements for close human–robot interaction and human–robot contact when the robot is operational. WG7 is intending to next explore the development of the following standards:

- an informative guidance document on the usage of ISO 13482;
- a validation and verification document for ISO 13482;
- normative human injury classification for robots for different types of users (adults, children, elderly persons, pregnant women, etc).

3.3. **Medical robots**

Emerging technologies present challenges to the regulatory processes for all areas, but medical robotics is especially difficult. The benefits and risks are to be managed properly and leveraging on medical standards is essential. For example, the US Food and Drug Administration (FDA) struggles to keep its regulatory processes and procedures aligned with the rapid pace of new medical technologies. There was a time when simpler individual devices were developed and submitted for regulatory clearance. The devices still provided necessary tools for medical procedures that sustain, repair, or improve the patient condition. As technology has advanced, so has the complexity of the review process as it has to be much more robust to meet the growing risks and challenges of maintaining patient safety.

Risks are part of doing business, and while there is no *acceptable level of risk* particularly in healthcare, managing risk is a daunting responsibility. Risk management is the key and utilizing medical device risk management standards throughout the process can make the difference. What makes a medical robot a robot is the level of autonomy which takes risk up to an even higher level than with other medical devices that only rely on human operation.

There is no harmonised definition of a medical robot as such, but experts working on this topic in IEC TC62/SC62A & ISO TC184/SC2 JWG9 *Medical electrical equipment and systems using robotic technology (Medical robots)*, have come up with the following possible suggestion: **ROBOT** or **ROBOTIC DEVICE** intended to be used as **MEDICAL ELECTRICAL EQUIPMENT (MEE)** or as **MEDICAL ELECTRICAL SYSTEMS (MES)**.\(^21\)

The industrial robot definition includes “automatically controlled,” although this robot type cannot perform surgical procedures or autonomous functions on behalf of the human which can have life or death implications. The key issue is...\(^21\) The words in small capitals are formally defined IEC terms.
the autonomy—the ability to perform intended tasks based on current state and sensing without human intervention.

Fortunately, the different groups are learning from each other. In July 2012, the Association for the Advancement of Medical Instrumentation (AAMI)\textsuperscript{22}, a US developer of medical devices standards, and the nuclear power industry held a workshop to exchange experiences managing risks in two of the most highly regulated industries in the world and determine the best practices applicable for each domain. In both industries, the risks are high, but the benefits are perceived to outweigh those. Also, the risk to operators/users and the public/patients must be considered and standards are instrumental in assisting manufacturers, operators, and regulators alike. International standards not only drive efficiencies, they also drive safety and efficacy and are a great leveraging tool for the medical device industry to ensure we have better and safer devices on the market.

3.4. **Boundary issues**

As new robots are developed, it is important to ensure boundaries between the various robot classes are clear. For example, the boundary between medical and non-medical robots is important because different regulatory frameworks are enforced. It must be noted that personal care robots may have both potential medical and non-medical applications. For example, assistive exoskeleton robots can be used for rehabilitation of injured people as a medical application, as well as physically helping, in a non-medical application, a healthy person to carry heavy loads. Other applications are not so clear, namely an assistive exoskeleton for improving the degraded mobility of healthy elderly people. For this, detailed work on the EC Machinery Directive and the EC Medical Device Directive is needed to identify key issues and provide appropriate guidelines.\textsuperscript{23}

4. **Moral and social projections**

4.1. **Performance metrics**

In industrial robotics, the usability of a robot system is linked to accuracy, repeatability, quality of service, and further well-defined, quantifiable metrics. In the case of service robotics, the overall system design might be application-oriented, which may mean lower precision and reliability. Service robots, especially personal service robots, must be more intuitive and require minimal maintenance and engineering skills to operate. The assessment of the core values of service robot systems will be via user acceptance, but this is hard to bind to any absolute scale. Nevertheless, performance metrics are being defined for specific application domains, such as robot vacuum cleaners. Even in the case of

\textsuperscript{22} AAMI: www.aami.org

\textsuperscript{23} IEC has initiated recently setting up a new working group to identify these boundaries.
the precision-oriented field of medical robots, accuracy is typically mis-measured and wrong/confusing numbers are reported [3].

4.2. 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.

It is commonly quoted that a medical product needs 10–15 years to grow from concept to full product. This long time-to-market requires product development to be managed carefully to ensure adequate resources. Intuitive Surgical Inc. leads the market with their surgical system being successfully applied as a “razor and razor blade” revenue model. They profit from robot sales, service contracts, and also from selling a lot of the laparoscopic tools, since those are sterilisable only 8-10 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 [4]. This also induced the morally questionable phenomenon that buying a da Vinci robot increases the number of prostatectomy procedures performed locally [5].

Safety is a key issue in all human–robot interactions, yet it is most critical in surgery where many kinds of errors may lead to critical conditions in the operating room. According to Satava [6], errors in interventional medicine can be categorised as: 1) commission: doing the wrong thing, 2) omission: not doing the right thing, and 3) execution: doing the right thing incorrectly.

These errors (either systematic or specific) can be traced back to human decision making, therefore—in classical surgery—the case is always the human surgeon’s responsibility. Extending this concept to robotic surgery leaves some ambiguity since it is generally not accepted to employ statistical calculations for evaluating individual risk.

4.3. 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 (i.e., medical applications), where relatives and friends would always assess and deal with hazards fundamentally differently. The relevant new standards must incorporate these human factors to ensure wide acceptance. In the meanwhile, 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 mean that there is an exponential rise in the number of hazardous incidents. For example, in robotic surgery, the
da Vinci system on its own gives rise to about 1.5 million procedures worldwide.

5. Conclusions

The paper has presented key issues that need to be addressed holistically by the robot stakeholder community now if more advanced service robots and assistive infrastructure are to be developed in the near future. This refers to creating normative data and methods for designing and testing the new robot systems to ensure acceptable levels of safety and performance. We need to work together to realise this, since international collaboration is vital to maximize the likelihood of success of any adopted strategy. With each information-exchange program and publication, and each meeting of standards experts with closer links to researchers, progress is being made. Both industry and regulatory bodies need better normative guidelines or managing risk in a dynamic, innovative, and global environment. Newly developing service robot standards along with well-grounded quality and risk management standards are essential for this toolbox.

References