Regulations and standards for Robotics and Autonomous Systems in the UK machinery sector

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ABSTRACT

The Health and Safety Executive (HSE) conducted research to identify safe implementation strategies for new and emerging technologies in the UK machinery sector. The research focused on how well existing standards and guidance apply to these technologies. While robotics and autonomous systems (RAS) served as a specific example during stakeholder workshops due to their embodiment of many new and emerging technology aspects, the project's overall scope is broader. This work also aimed to address scenarios where humans collaborate with new technologies to control machinery.

The research aimed to answer the following questions:

- What is already known about the coverage of existing regulations, standards and guidance with regard to new and emerging technologies?
- Where does industry turn to for guidance regarding implementation of new and emerging technologies?
- Which topic areas require immediate help and guidance, while the current standards catch up with new and emerging technologies?

The research adopted a three-step approach to answer the above questions. First, a review of relevant standards and guidance documents was conducted to identify potential gaps in their coverage of these novel technologies. Second, a questionnaire was sent out to relevant machinery manufacturers and vendors and industry organisations, with an invitation to attend the workshops and/or to complete and return the questionnaire. Third, to complement the standards review and gain qualitative insights, two interactive workshops were undertaken. Participation included representatives from manufacturers, system integrators, end users, and academia. The workshop analysis, which is the focus of this paper, considered five specific new technologies: Autonomous Mobile Robots (AMR), Autonomous Agricultural Vehicles (AAV), Collaborative Robot Applications (CRA), Artificial Intelligence/Machine Learning (AI/ML), and Cyber Security (CS).

The first workshop covered the use of AAVs in the agricultural sector, whereas the second workshop looked at the use cases for AMRs and Collaborative Robot Applications in the manufacturing sector. The workshops used case studies to consider different levels of autonomy and potential future implementations of innovative technologies, for example, using machine learning to control equipment and make decisions to improve safety.

The research identified areas where the use of new technologies meant that there were different risks associated with machinery. The research concluded that the current UK legislation can be applied to new technologies, but that there may be a need for industry guidance to help in those areas where standards are yet to catch up with recent technological innovations. The outcomes of this exercise highlight areas of future research, suggest areas for development of industry guidance, and will possibly feed into standards development to help ensure safe design and implementation of autonomous systems in the UK and beyond.

1. INTRODUCTION

1.1 Background

Occupational health and safety in the UK is primarily governed by the Health and Safety at Work *etc*. Act 1974, which establishes general duties for both employers and employees. The Health and Safety Executive enforces this Act and oversees the creation of specific regulations. HSE are also the market surveillance authority for product safety of equipment used for work including machinery. The product safety framework is completely separate to the Health and Safety at Work etc Act and is owned by the Office for Product Safety and Standards (OPSS) that sits within the Department for Business and Trade. Legislation such as the Supply of Machinery (Safety) Regulations 2008 require manufacturers to ensure that their products are safe before being put into use British, European, and international standards, also complement these regulations by providing detailed requirements for equipment manufacturers, systems integrators, and end users. Guidance documents, either in the form of technical reports (TR) from standards organisations, or specifically written by industry bodies, help by providing sector, or machinery, specific guidance to assist in interpreting the standards or filling in gaps in the standards

1.2 Challenges of new and emerging technologies

Recent developments in automation have introduced new equipment such as AMR, AAV and other new technologies. An increased reliance on software for safety means that cyber security is of greater importance and the use of artificial intelligence (AI) for control in complex environments potentially introduces new risks that were not considered in the previous generation of regulations, standards and guidance. Integrating these technologies within existing machinery design presents unique challenges in ensuring their safe and reliable operation. Concerns exist regarding the adequacy of current standards and guidance documents to comprehensively address potential safety risks in the machinery sector. Standards may also differ across different trading blocs, and there is already divergence with the EU. There is also the potential for regulatory divergence i.e. Supply of Machinery as the Machinery Directive is reviewed and revised. Potential inconsistencies in implementation, validation, and verification across sectors and applications raise further concerns.

1.3 Research aims

HSE conducted research to identify safe implementation strategies for new and emerging technologies in the UK machinery sector. The research focused on how well existing standards and guidance apply to these technologies. While robotics and autonomous systems served as a specific example during stakeholder workshops due to their embodiment of many new and emerging technology aspects, the project's overall scope is broader. This work also aimed to address scenarios where humans collaborate with new technologies to control machinery.

This research aimed to answer the following questions:

- **Existing Regulatory Landscape:** What is the current understanding of how existing regulations, standards, and guidance documents address the safety implications of new and emerging technologies? Are there gaps or areas where these resources need to be updated?
- **Industry Guidance Needs:** Where does the machinery sector typically look for guidance when implementing these new technologies? Identifying these existing resources can help assess their effectiveness and potential shortcomings.
- **Prioritizing Safety Gaps:** Which specific areas of technological development require immediate attention in terms of safety protocols and guidance? This will help prioritize efforts to ensure worker safety while new standards are developed.

The identification and bridging of potential gaps in current standards and guidance documents, while new or updated ones are being developed, can help ensure the safe and responsible integration of new and emerging technologies in the UK's machinery sector. Alignment with significant trading partners should also be considered.

1.4 Approach

The research adopted a three-step approach to answer the above questions.

1. A review of relevant standards and guidance documents was conducted to identify potential gaps in their coverage of these novel technologies.
2. A questionnaire was sent out to relevant machinery manufacturers and vendors and industry organisations, with an invitation to attend the workshops and/or to complete and return the questionnaire.
3. To complement the standards review and gain qualitative insights, two interactive workshops were undertaken. Participation included representatives from machinery manufacturers, system integrators, end users, and academia. The workshop analysis, which is the focus of this paper, considered five specific new technologies: Autonomous Mobile Robots, Autonomous Agricultural Vehicles, Collaborative Robot Applications, Artificial Intelligence/Machine Learning, and Cyber security.

2. REVIEW OF IDENTIFIED STANDARDS AND GUIDANCE

The focus of the review on a limited number of key machinery safety standards and guidance documents was to identify gaps in how they address the use of new and emerging technologies. A summary of the findings of the standards and guidance review are presented below.

The research team examined machinery safety standards from established international organizations, including the European Union (EU), the International Organization for Standardization (ISO), and the International Electrotechnical Commission (IEC). They also considered some standards from national bodies like the American National Standards Institute (ANSI) and the British Standards Institute (BSI).

The review went beyond just the standards themselves. The team looked at relevant topic guidance, which typically came from technical reports of the standards organizations, relevant industry bodies, and government organizations. For example, the National Cyber Security Centre (NCSC) has produced guidance on cybersecurity for autonomous systems.

To ensure their review was relevant the team went beyond the standards and guidance identified in a previous project completed in 2020. Recognizing the rapid pace of standards development, they also included some key documents published after the project's closure.

The standards and guidance review, that considered how well they covered the application of new and emerging technologies, highlighted several common themes, the key ones are listed below, and associated concerns raised by participants.

Machinery Lifecycle Activity coverage

- The reviewed design standards effectively focused on the crucial stages required for the design process, such as risk assessment and safety requirements capture. However, for a holistic approach to the machinery lifecycle, including references to guidance on later stages, such as decommissioning, would be beneficial for users to facilitate a joined-up approach.
- Both machinery design and risk assessment standards currently lack, or do not signpost, guidance on the competence for individuals involved in various lifecycle stages.

Cybersecurity

- Current safety of machinery standards lack reference to guidance on tailoring generic industrial and automation systems cyber security standards to the unique context of machinery.
- The diverse, varied and adaptable nature of robotic systems necessitates the development of sector specific guidance that interprets existing cyber security standards for robotic systems, thereby ensuring their effective implementation.

Artificial Intelligence and Machine Learning

- Existing design and risk assessment standards don't fully address safe and reliable use of AI and ML in machinery control.
- While frameworks exist to ensure trustworthy AI/ML systems, their effectiveness in developing safe and reliable AI-powered machinery control systems remains unclear due to a lack of documented industrial applications.
- Current safety standards lack specific requirements for AI/ML-based control systems, including data quality, model explainability, and mitigating data/model bias, for those machinery control systems that relay on data.
- PD CEN ISO/TR 22100-5:2021 offers guidance on considering AI/ML safety implications during risk assessments (ISO 12100). However, it doesn't address integrating AI/ML into safety-related control systems.
- PD ISO/IEC TR 5469:2024 focuses on safe AI integration in safety-critical systems. The document describes various aspects related to the use of AI within safety-related functions, ensuring safety for AI-controlled equipment, and designing safety-related functions using AI systems.
- There's no widely adopted industry-specific guidance for crucial aspects like training data bias/accuracy and model explainability/trust in AI-based machinery control systems.

2.2 QUESTIONAIRE

In preparation of the workshops, a questionnaire was sent out to organisations interested in the topic area, but were unable to attend, and those confirmed workshop participants. The questionnaire explored topics central to both workshops, such as utilising new technologies, adherence to standards, and areas of involvement within these emerging fields. The questionnaire also asked about the challenges that the participants may had faced when working with these new technologies.

By analysing the responses received, the HSE team gained valuable insights into the perspectives of external stakeholders, which were then shared at the workshops for enhanced understanding.

2.3 STAKEHOLDER WORKSHOPS FINDINGS

HSE consulted with stakeholders with an interest in design, implementation, or use of autonomous systems that could involve new and emerging technologies. Participants considered Autonomous Agricultural Vehicles (AAVs) in the first workshop, while Autonomous Mobile Robots (AMRs) and Collaborative Robot Applications were considered in the second workshop. Participants in both workshops said that such technologies are being introduced in the UK now. However, they thought barriers existed that were preventing widespread adoption.

Other related topics considered included artificial intelligence, machine learning as applied to intelligent machine vision, control and safety systems, network connectivity and cyber security.

The workshops centred around case studies to consider different levels of autonomy and potential future implementations of innovative technologies. This paper presents five key issues discussed by the workshop participants regarding their experience and opinions on emerging technologies and their coverage in relevant standards.

The following discussions are grouped into themes identified in the analysis of the workshop outcomes.

UK regulatory framework post EU exit

Participants were concerned about the uncertainty with regulation relating to autonomous systems use in the UK in agricultural and machinery sectors. They were concerned that they did not know whether the UK regulations would diverge from the new European machinery safety regulations, Regulation 2023/1230/EU – machinery, when published and if so, then what would this diversion look like. They also stated that this uncertainty risked a lack of investment and research, potentially delaying widespread adoption of robotic and autonomous systems applications.

Competency

Participants raised concerns about end users limited understanding of autonomous system operating modes and risks, potentially leading to incidents during operation or maintenance. Consistent and clear guidance, beyond existing design standards, is essential for safe equipment utilisation.

Navigating complex environments: To extract maximum benefit, AMRs need to operate in complex environments. This demands specialised safeguards, safe work systems, and targeted training that addresses the unique risks associated with such settings.

Grasping risks and responsibilities: Participants highlighted a lack of understanding regarding the implications of AI and cyber security on safety, coupled with uncertainties about their roles in risk assessment, validation, and ongoing system management. Finding qualified people to address these gaps remains a key challenge.

Concerns were expressed about a lack of understanding of integration-related risks associated with autonomous systems. Integrators require robust technical expertise in AI and cyber security to ensure system safety and resilience.

It was stated that developing competence in this area is challenging, in the absence of consistent or coherent standards and guidance. It was generally agreed that lack of guidance on the operation of these systems is a prime concern, while design issues can be dealt with by new and existing international standards.

Risk assessment

Participants highlighted the unique hazards and evolving risks associated with AMRs. These risks vary depending on the application, situation, operating environment, and the level of interaction between humans and autonomous equipment.

Participant stated that pinpointing who is primarily responsible for human safety in these systems can be challenging. Sometimes, designers rely heavily on people to maintain safe operation. Risk assessments sometimes address this reliance through administrative controls; however such controls occupy a lower tier in the hierarchy of controls and as such are less effective than other options.

Therefore, participants expressed a need for new, sector-specific guidance on the application, operation, and risk assessment of AMRs. This guidance would benefit manufacturers, systems integrators, and end users by clarifying who should be involved in the risk assessment process and at what stage.

Although the issue on risk assessment was discussed for AMRs, it is a key issue to consider for the all the new technologies that were in scope of this work.

Factors impacting Autonomous Agricultural Vehicle operation

Participants raised concerns about the following potential safety issues with AAVs:

- Misuse: AAVs could be misused in a number of ways, including through cyber-attacks, vandalism, and joyriding.
- Weather conditions: The effectiveness of some people/object detection technologies can be reduced in poor weather conditions, which could increase the risk of accidents when AAVs are used in these circumstances.
- Maintaining safety in normal operation and inappropriate use of AAVs beyond their design parameters could occur during maintenance activities.
- Terrain: The risk assessment for AAVs should consider the potential challenges of operating these vehicles in complex and challenging terrain.
- Public access: Public footpaths and the right to roam could make it difficult to deploy AAVs in many areas of the country.

Monitoring of Autonomous Agricultural Vehicles in the field

Participants discussed the advantages and disadvantages of monitoring AVVs, where this monitoring could be local or remote. It was suggested that the AAV system should use a supervisory function that confirms the presence of a human supervisor and if there was no response then the AAV would cease operation. Participants suggested that remotely monitoring multiple AAVs would be one way to make it economical; the number of AAVs that could be safely monitored would need to be determined by risk assessment.

United Kingdom Conformity Assessment (UKCA) conformance in changing environments and applications

Participants noted that when procuring an autonomous system such as an AAV, AMR or Collaborative Robot Application, the end user will get a declaration of conformity stating that the system is ‘safe’. However, the end user might not realise that if the equipment is operating in a complex and evolving environment, any changes in the environment, or any modifications made to the application, could invalidate the boundaries that were used for the conformity assessment or introduce risks not foreseen by the designer.

Careful consideration is needed when repurposing Robotics and Autonomous Systems (RAS) to carry out a different task, to determine whether recertification is needed. An area of concern for participants was their uncertainty regarding the extent of work needed to meet product safety regulatory requirements. Their concerns were around what needed to be done, and by whom, for the new autonomous system or robot application to be considered safe in its new function. Participants agreed that there is a need for all stakeholders to work together to develop a risk assessment and validation plan that ensures safety over the lifetime of the system. Participants thought that guidance on the end users’ responsibilities for validating new applications and managing the ongoing risks during operation would be beneficial to help accelerate adoption of these technologies.

3. KEY FINDINGS

The key finding of the work undertaken are summarised below.

- Evolving Risks: The emerging technologies discussed in this paper are different from traditional machinery safety in that the risks can change over time. This means that the requirements in design standards which do not cover lifecycle activities will not be enough to ensure the safety of the machinery over its lifetime.
- End user knowledge: End users can lack an adequate understanding of AI-based system behaviours and this could lead to increased risk to people.

- UKCA marking: If risks change after placing the machine on the market, then it might no longer be sufficient to simply follow the operation manual for the machine and expect it to remain safe. End users of machines are being given more responsibility for safety and they may not be aware of this.
- Ongoing management of cyber security, AI enabled learnt machine behaviour, complex evolving environments and decommission of machinery were in general not adequately covered in the standards reviewed and were all identified as gaps for end users of autonomous systems.
- Incomplete Standards: Existing standards lack detailed requirements for newer technologies like autonomous systems and AI-based machinery control, particularly regarding their interaction with other people. However, new standards are being developed that aim to deal with these issues. With new standards there will likely be a requirement for sector specific guidance to aid their interpretation.

4. CONCLUSIONS

This work concludes that guaranteeing the safety of machinery operations in the face of rapidly evolving technologies demands a multi-pronged approach. Central to this is a robust and adaptable regulatory framework, bolstered by supportive standards and industry-specific guidance. Collaborative research plays a crucial role in bridging knowledge gaps and optimising existing safety protocols for new technologies. This continuous process of regulation, research, and industry collaboration is vital in the dynamic landscape of emerging technologies, ensuring their safe integration and future development.

The goal- setting nature of the UK's regulatory framework provides a good foundation for adaptability, allowing it to address evolving risks associated with new technological advancements. However, industry sector guidance is needed for areas where standards have not caught up with technological innovations.

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