

# ISO 31101:2023-11 (E)

## Robotics - Application services provided by service robots - Safety management systems requirements

---

| <b>Contents</b>     |   | <b>Page</b> |
|---------------------|---|-------------|
| <b>Foreword</b>     |   | <b>v</b>    |
| <b>Introduction</b> |   | <b>vi</b>   |
| <b>1</b>            | <b>Scope</b>  | <b>1</b>    |
| <b>2</b>            | <b>Normative references</b>   | <b>1</b>    |
| <b>3</b>            | <b>Terms and definitions</b>  | <b>1</b>    |
| <b>4</b>            | <b>Context of the organization</b>  | <b>8</b>    |
| 4.1                 | Understanding the organization and its context                            | 8           |
| 4.2                 | Understanding the needs and expectations of interested parties            | 9           |
| 4.3                 | Determining the scope of the application service safety management system | 9           |
| 4.4                 | Application service safety management system                              | 9           |
| <b>5</b>            | <b>Leadership</b>   | <b>10</b>   |
| 5.1                 | Leadership and commitment   | 10          |
| 5.2                 | Policy  | 10          |
| 5.3                 | Roles, responsibilities and authorities                                   | 11          |
| <b>6</b>            | <b>Planning</b>   | <b>11</b>   |
| 6.1                 | Actions to address risks and opportunities                                | 11          |
| 6.2                 | Application service safety objectives and planning to achieve them        | 11          |
| 6.3                 | Planning of changes   | 12          |
| 6.4                 | Safety risk assessment  | 12          |
| 6.4.1               | General   | 12          |
| 6.4.2               | Preparation of safety risk assessment                                     | 12          |
| 6.4.3               | Safety risk analysis  | 13          |
| 6.4.4               | Safety risk evaluation  | 14          |
| 6.5                 | Activities for safety risk reduction                                      | 14          |
| 6.5.1               | General   | 14          |
| 6.5.2               | Determination of safety risk reduction measure                            | 14          |
| 6.5.3               | Determination of compliance obligations on the operation                  | 15          |
| 6.5.4               | Planning implementation of the safety risk reduction measures             | 16          |
| <b>7</b>            | <b>Support</b>  | <b>16</b>   |
| 7.1                 | Resources   | 16          |
| 7.2                 | Competence  | 16          |
| 7.3                 | Awareness   | 17          |
| 7.4                 | Communication   | 17          |
| 7.4.1               | General   | 17          |
| 7.4.2               | Internal communication  | 18          |
| 7.4.3               | Communication with interested parties                                     | 18          |
| 7.5                 | Documented information  | 18          |
| 7.5.1               | General   | 18          |
| 7.5.2               | Creating and updating documented information                              | 18          |
| 7.5.3               | Control of documented information   | 18          |
| <b>8</b>            | <b>Operation</b>  | <b>19</b>   |
| 8.1                 | Operational planning and control  | 19          |
| 8.2                 | Communication with users  | 19          |
| 8.3                 | Consideration for the third party of application service                  | 20          |
| 8.4                 | Emergency preparedness and response                                       | 20          |
| 8.5                 | Managing hazardous events   | 21          |

|                     |  |           |
|---------------------|--|-----------|
| <b>9</b>            | <b>Performance evaluation</b> .....  | <b>22</b> |
| 9.1                 | Monitoring, measurement, analysis, and evaluation .....  | 22        |
| 9.2                 | Internal audit .....   | 23        |
| 9.2.1               | General .....  | 23        |
| 9.2.2               | Internal audit programme .....   | 23        |
| 9.3                 | Management review .....  | 24        |
| 9.3.1               | General .....  | 24        |
| 9.3.2               | Management review inputs .....   | 24        |
| 9.3.3               | Management review results .....  | 24        |
| <b>10</b>           | <b>Improvement</b> .....   | <b>24</b> |
| 10.1                | Continual improvement .....  | 24        |
| 10.2                | Nonconformity and corrective action .....  | 25        |
| <b>Annex A</b>      | <b>(informative) Example of interested parties in application service and relationship to the defined terms</b> .....  | <b>26</b> |
| <b>Annex B</b>      | <b>(informative) Classification of the relationship between operation contents of application service and robot use restriction intended by robot system providers</b> ..... | <b>27</b> |
| <b>Annex C</b>      | <b>(informative) Examples of information for use of service robots</b> .....   | <b>29</b> |
| <b>Annex D</b>      | <b>(informative) Examples of hazards in operation and their causes</b> .....   | <b>33</b> |
| <b>Bibliography</b> | .....  | <b>41</b> |