Risk analysis of complex medical devices:
Comparison of the use of ISO 31000, ISO 14971 and STAMP/STPA for microprocessor-controlled prosthetic knees

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Background
The challenge

For complex medical devices ISO/EN 14971 does not cover EU regulators’ essential requirements and is complemented by other standards and a periodic audit process.
Objective

- Compare the risk analysis process of ISO 14971, ISO 31000 and STAMP/STPA
- How are the differences relevant to risk management of complex medical devices?
### General

<table>
<thead>
<tr>
<th>ISO 31000</th>
<th>ISO 14971</th>
<th>STAMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidelines</td>
<td>Guidelines (harmonized standard)</td>
<td>Method</td>
</tr>
</tbody>
</table>
Core concepts

<table>
<thead>
<tr>
<th></th>
<th>ISO 31000</th>
<th>ISO 14971</th>
<th>STAMP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accident</strong></td>
<td>“Occurrence or change of a particular set of circumstances”</td>
<td>Undefined</td>
<td>“An undesired and unplanned event that results in a loss (including loss of human life or injury, property damage, environmental pollution and so on)”</td>
</tr>
<tr>
<td><strong>Harm</strong></td>
<td>Undefined</td>
<td>“Physical injury or damage to the health of people, or damage to property or the environment”</td>
<td>Undefined</td>
</tr>
</tbody>
</table>

Differences in nomenclature
## Risk Analysis

<table>
<thead>
<tr>
<th>ISO 31000</th>
<th>ISO 14971</th>
<th>STAMP/STPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic and abstract</td>
<td>Manufacturer selects</td>
<td>Systematic approach</td>
</tr>
<tr>
<td>model</td>
<td>appropriate methods</td>
<td>(STPA)</td>
</tr>
</tbody>
</table>

- Manufacturer defines acceptable risks
- Importance of communication and documentation
Conclusions

How are the differences relevant to risk management of complex medical devices?

- STAMP/STPA provides a more systematic approach to analyse risks originating from interaction between the components of a complex system.
- STAMP/STPA designed to address risks through design.
- Is STAMP/STPA more cost effective for regulatory compliance?