

# ISO/TS 20405:2018-05 (E)

## Health informatics - Framework of event data and reporting definitions for the safety of health software

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	Principles, data concepts and process model .....	2
4.1	General .....	2
4.2	Principles .....	3
4.2.1	General .....	3
4.2.2	Proactivity .....	3
4.2.3	Objectivity .....	3
4.2.4	Accountability .....	3
4.2.5	Transparency .....	3
4.2.6	Preparedness .....	3
4.2.7	Comprehensiveness .....	4
4.3	Data concepts .....	4
4.3.1	General .....	4
4.3.2	Accuracy .....	4
4.3.3	Timeliness .....	4
4.3.4	Comparability .....	4
4.3.5	Usability .....	4
4.3.6	Relevance .....	5
4.4	Process model .....	5
4.4.1	General .....	5
4.4.2	Recording .....	5
4.4.3	Analysing .....	5
4.4.4	Reporting .....	5
5	Patient safety data elements .....	6
5.1	General .....	6
5.2	Event information .....	6
5.2.1	General .....	6
5.2.2	Event identification .....	6
5.2.3	Event date and time .....	6
5.2.4	Report date .....	6
5.2.5	Event reporter information .....	6
5.2.6	Event supplementary information .....	7
5.3	Event categorization .....	7
5.4	Event classification .....	7
5.4.1	General .....	7
5.4.2	Information input/output errors .....	8
Annex A (informative)	Information on various health software surveillance systems .....	13
Bibliography .....		15