

# Contents

|          |  |           |
|----------|--|-----------|
| <b>1</b> | <b>Purpose and Objective of This Guide</b>                               | <b>5</b>  |
| <b>2</b> | <b>Product Safety and Information</b>                                    | <b>8</b>  |
| 2.1      | The Role of Information in Product Safety                                | 8         |
| 2.2      | From Risk Assessment to Safety Note or Warning Message                   | 9         |
| 2.3      | Types of Safety-Related Information                                      | 12        |
| 2.4      | Tasks and Opportunities for Technical Communicators                      | 13        |
| <b>3</b> | <b>Legal Requirements for Safety-Related Information</b>                 | <b>15</b> |
| 3.1      | Germany, Austria, Switzerland  | 15        |
| 3.1.1    | G: German Product Safety Law and its Regulations                         | 15        |
| 3.1.2    | Medical Product Law  | 15        |
| 3.1.3    | A: Austrian Product Safety Law and its Regulations                       | 16        |
| 3.1.4    | CH: Swiss Federal Law on Product Safety                                  | 17        |
| 3.2      | Requirements in European Law   | 18        |
| 3.2.1    | Product Safety Directive 2001/95/EC                                      | 18        |
| 3.3      | Specific EC Directives (Particularly, CE Marking)                        | 19        |
| 3.3.1    | EMC Directive 2014/30/EU   | 19        |
| 3.3.2    | Low-Voltage Directive 2014/35/EU   | 19        |
| 3.3.3    | Machinery Directive 2006/42/EC   | 20        |
| 3.3.4    | Medical Devices Directive 93/42/EEC                                      | 20        |
| 3.3.5    | In-vitro Diagnostics Directive 98/79/EC                                  | 21        |
| 3.3.6    | Pressure Equipment Directive 2014/68/EU                                  | 22        |
| 3.3.7    | ATEX Directive 2014/34/EU  | 22        |
| 3.3.8    | Toy Safety Directive 2009/48/EC  | 23        |
| 3.4      | USA  | 23        |
| 3.4.1    | Legal Basics   | 23        |
| 3.4.2    | Practical Application  | 25        |
| 3.5      | Brazil   | 27        |
| 3.6      | Russia   | 28        |
| 3.7      | People's Republic of China   | 29        |
| 3.8      | Examples of Requirements in Various Industries                           | 31        |
| 3.9      | Requirements from Case Law   | 33        |
| <b>4</b> | <b>Requirements for Safety-Related Information in Relevant Standards</b> | <b>34</b> |
| 4.1      | European and International Standardization – EN, ISO, IEC                | 34        |
| 4.1.1    | Cross-Sector Standards   | 34        |
| 4.1.2    | Mechanical Engineering   | 38        |
| 4.1.3    | Medical Devices  | 40        |
| 4.1.4    | Household Appliances   | 43        |
| 4.2      | US Standardization – ANSI and Beyond                                     | 44        |
| 4.2.1    | ANSI Z535.1 to 6   | 44        |
| 4.2.2    | Comparison of ISO/IEC 82079-1 and ANSI Z535.6                            | 45        |

|          |   |           |
|----------|---|-----------|
| <b>5</b> | <b>Recommendations for Implementation</b>                                     | <b>51</b> |
| 5.1      | Basics of Structuring and Presentation of Safety Information in Instructions  | 51        |
| 5.2      | Safety Notes  | 53        |
| 5.2.1    | Structure and Content of the “Safety” Chapter                                 | 53        |
| 5.2.2    | Recommendations for design of safety notes                                    | 56        |
| 5.3      | Warning Messages in Context   | 56        |
| 5.3.1    | Structure, Content and Placement of Warning Messages                          | 57        |
| 5.3.2    | Recommendations for Design of Warning Messages                                | 58        |
| 5.3.3    | Additional Symbols and Pictograms (Warnings, Mandatory Actions, Prohibitions) | 60        |
| 5.3.4    | Translation of Signal Words   | 64        |
| 5.4      | Warning Signs   | 68        |
| <b>6</b> | <b>Glossary</b>   | <b>70</b> |
| <b>7</b> | <b>Abbreviations and Bibliography</b>   | <b>75</b> |
| 7.1      | List of Abbreviations   | 75        |
| 7.2      | List of Cited Laws, Directives, and Standards                                 | 76        |
| 7.2.1    | Laws  | 76        |
| 7.2.2    | EU Directives   | 77        |
| 7.2.3    | Standards   | 77        |
| 7.3      | Literature  | 79        |