

Overview of ISO CD 5137

Chapter structure

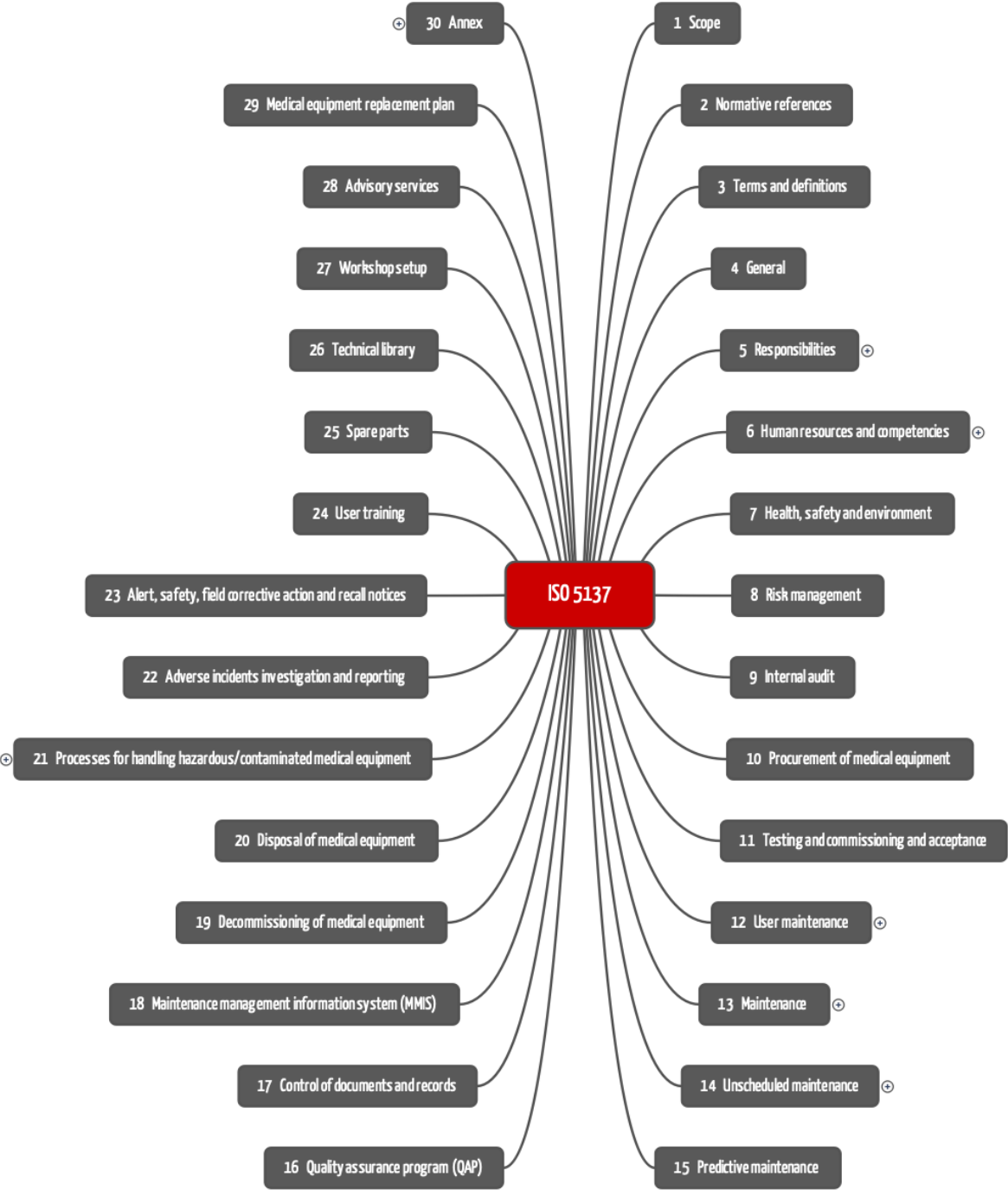


Fig. 1: Chapter structure of ISO 5137

Short descriptions of the chapters

The following table describes the first 20 chapters of the standard as examples.

Chapter	Requirement	Comment
4	General requirements for the maintenance program such as minimizing equipment downtime.	
5	Extensive list of responsibilities (see above)	
6	Requirements for the definition of the competencies (see above)	
7	The national requirements for health and environmental protection must be met.	Only one sentence
8	The health institution must conduct risk management.	The standard refers normatively to ISO 14971, but does not address it in the chapter.
9	Demand for internal audits	The chapter is very short. The requirements of ISO 13485 for internal audits are much more comprehensive.
10	Purchasing must comply with national regulations.	The standard contains only two sentences. Concrete specifications on what purchasing has to pay attention to can only be found in the appendix.
11	The standard requires a test of the devices before their use, if necessary, even a recertification(?!).	It is unclear how the authors come up with the flowchart. Its logic is not always comprehensible and is not explained in the text.
12	The users(?) are responsible for basic maintenance. This includes cleaning, inspection, storage and documentation.	Some of the requirements seem trivial, others arbitrary. It is not clear why the authors assign these tasks to the users.
13	The standard divides maintenance into planned preventive maintenance, calibration and routine inspection. The health institutions should determine the frequencies for maintenance and use checklists for this purpose.	Why the authors list the objectives of preventive maintenance in the normative text and not in the recitals or the annex is not clear. It seems that the authors do not know the definition of calibration.

14	In the case of unplanned maintenance, for example, the bESPs are to document the parts they need for this. Then, if necessary, they should test the electrical safety and "calibrate" the device.	
15	In addition to preventive maintenance, the standard also provides for predictive maintenance. The bESPs are to develop an algorithm for this purpose.	It is unclear which devices this requirement refers to and how the authors arrived at these requirements.
16	Now follows the requirement for a quality assurance program with structures and processes.	It is surprising that the standard does not define a program into which the other requirements are incorporated, as ISO 13485 does, for example.
17	Requirements for control of documents and records follow in three sentences.	
18	Having already been presupposed in previous chapters, now comes the requirement for a "Maintenance Management Information System (MMIS)".	The standard determines the "modules" that this MMIS should contain.
19	Operators must regulate decommissioning, complying with national requirements for decommissioning ionizing radiation equipment, for example.	
20	Disposal must also be regulated and comply with national requirements.	The three sentences are not very enlightening.