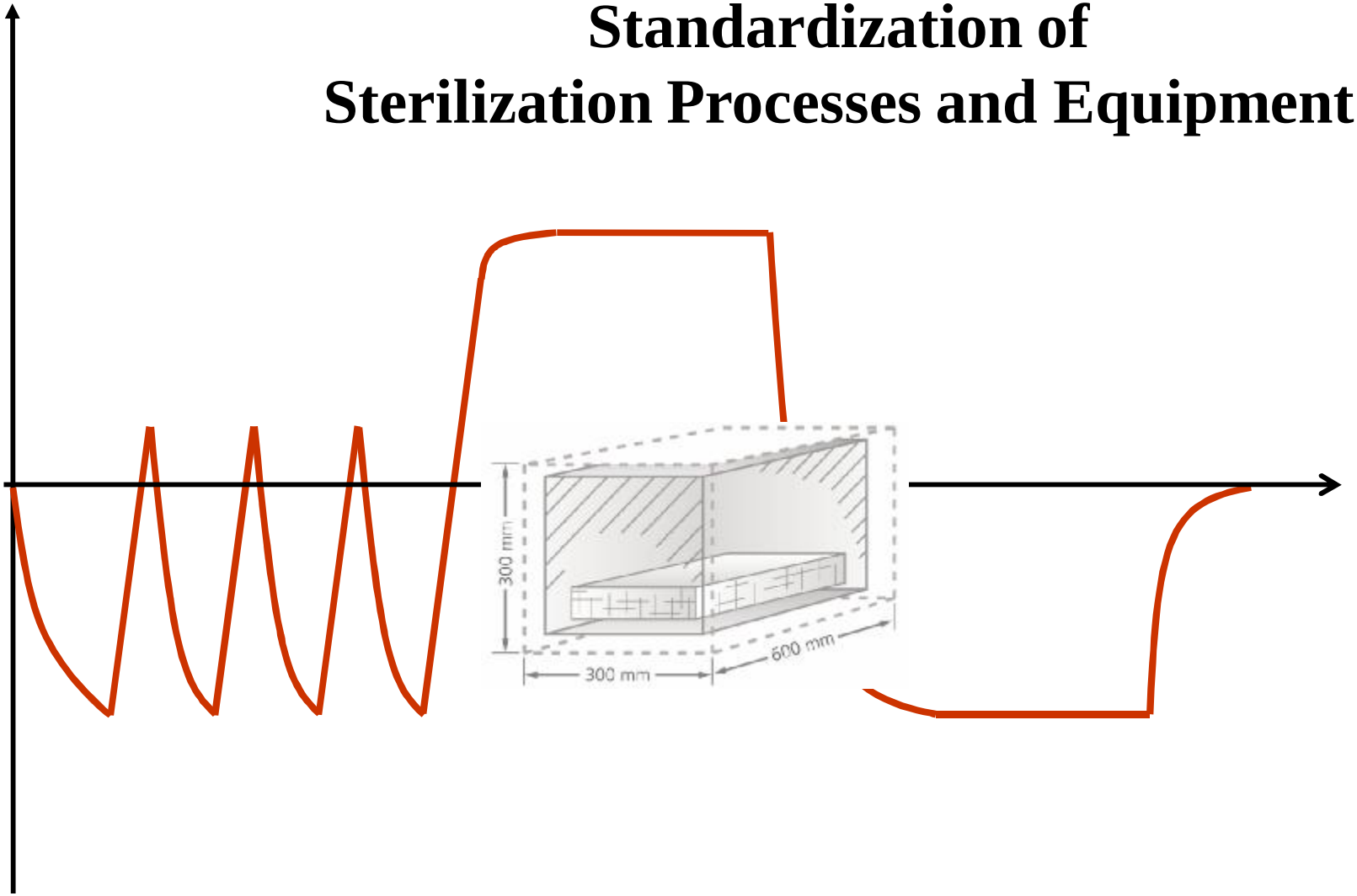
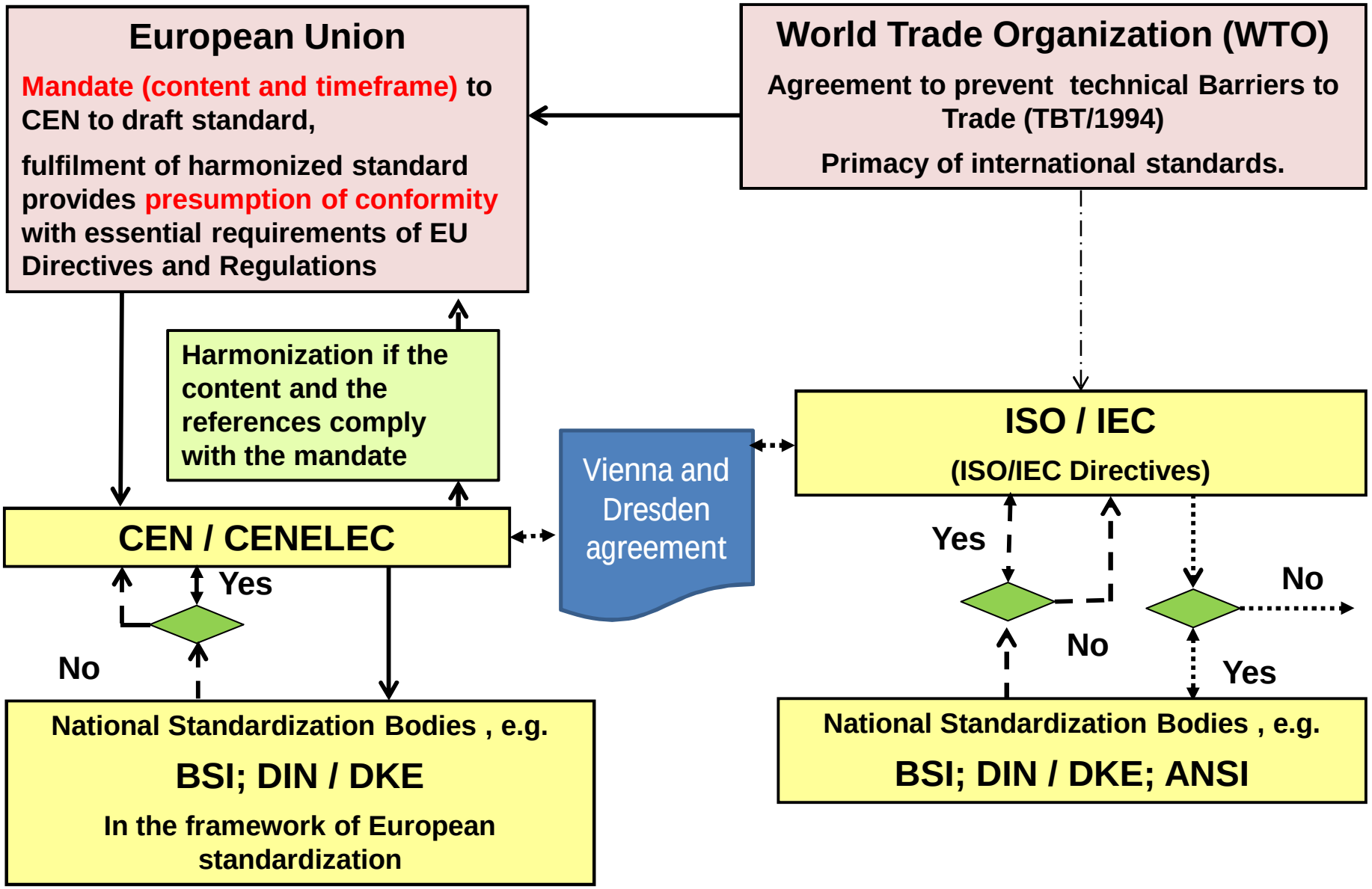
# International and European Standardization of Sterilization Processes and Equipment



# Standards for sterilization in health care settings

| EN (16) | EN ISO (29) | ISO (3) |
|---|---|---|
| | | ISO/TS 11139, Definitions |
| | EN ISO 17664, Information for reprocessing | |
| EN 556-1 and -2 „STERILE“ | EN ISO 14937, Sterilization, general<br>EN ISO 11135-1 and -2, EO<br>EN ISO 17665-1 and -2 , Moist heat<br>EN ISO 25424, LTSF sterilization | ISO/TS 17665-3, Product families |
| EN 285, Large steam sterilizer<br>EN 1422, EO sterilizer<br>EN 13060, Small steam sterilizer<br>EN 14180, LTSF Sterilizer<br>EN 16442, Storage cabinet | *Process standards include characterization of equipment, and testing of equipment .* | |
| | EN ISO 15883-1 to -7, Washer-disinfector | |
| EN 868-2 to -9, Packaging | EN ISO 11607-1 and -2, Packaging<br>ISO/TS 16775, Packaging | |
| | EN ISO 11138-1 to -6, Biological Indicators<br>EN ISO 14161, Guidance biolog. Indicators | |
| EN 867-5, Chem. Indikators | EN ISO 11140-1, -3 and -4, Chem. Indicators<br>EN ISO 15882, Guidance chem. Indicators | ISO 11140-5, Chemical indicators |
| | EN ISO 18472, Resistometer | |

# Standardization bodies



# Conformity with EU Directives

**International standards are market-driven and support economic operators.**

**Harmonized European standards are mandated and support legal acts, the free trade becoming a second-rate aim.**

**Route d) is an option proposed in ISO Global Relevance policy:**

**ISO standard contains only core requirements, additional requirements are addressed through a separate EN in support of the core ISO standard.**

# The founding Principles of Standardization (WTO)

## 1. Transparency

Publication of work programme and draft standards, take comments into account in the further consideration of the standard.

## 2. Openness

Participation of all interested parties.

## 3. Impartiality and consensus

Take into account the views of all parties concerned and to reconcile any conflicting arguments.

## 4. Relevance and effectiveness

**Aim-oriented response to regulatory and market needs, based on the state of the art; requirements based on principle of verifiability and performance rather than design or descriptive characteristics; for conformity assessment neutrality principle applies.**

## 5. Coherence

**Avoid conflicting international standards, duplication of, or overlap with.**

## 6. Developing country interests

# Principles of drafting standards

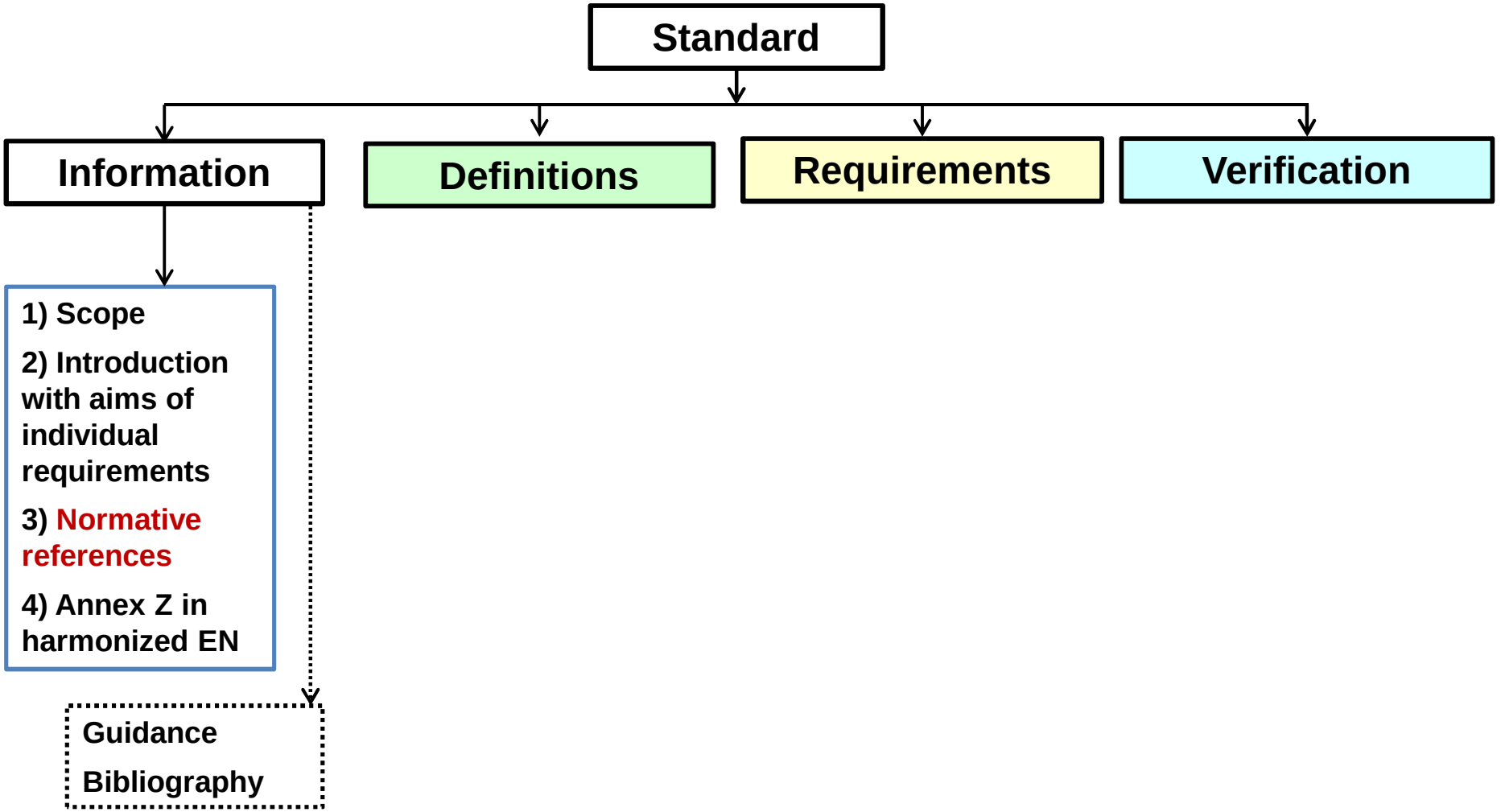
**The overriding aim of a standard is to ensure fitness for purpose of the product concerned (aim-oriented approach) [ISO/IEC Directives].**

**An ISO standard should represent a single solution of global relevance:**

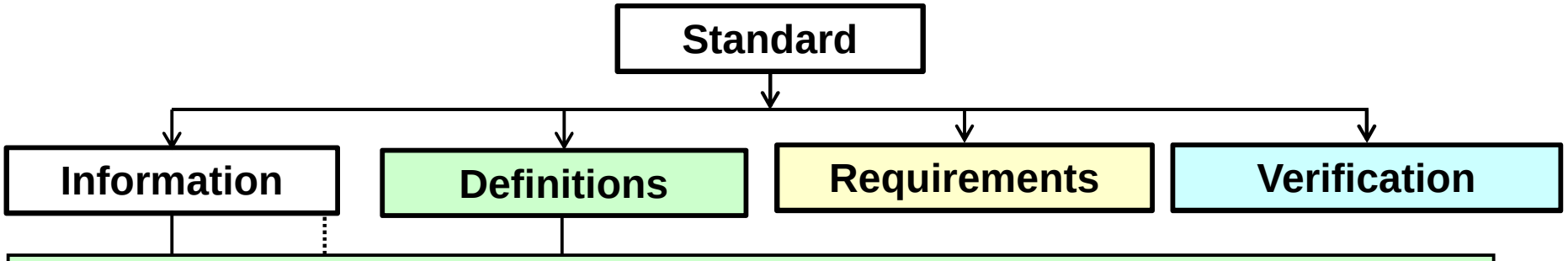
- **one concept,**
- **one definition,**
- **one specification,**
- **one verification procedure.**

**Avoidance of duplication is a general principle in the methodology of standardization.**

# The Elements of a standard (ISO/IEC Directives)



# The Elements of a standard (ISO/IEC Directives)

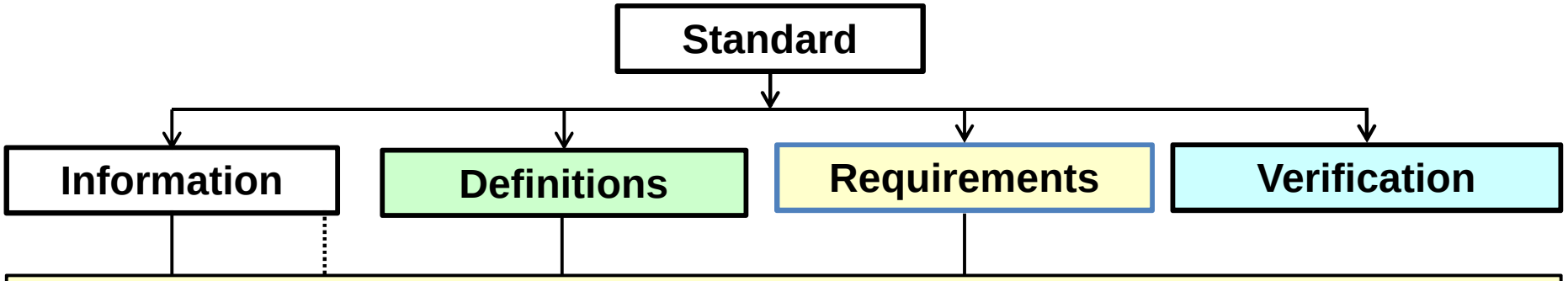



*Negative example:*

"Risk" means:

- § the combination of the probability of an event and its consequence; consequence means positive or negative effect, e.g. on economic profit or loss, see ISO/IEC Guide 73 and ISO 31000, or
- § a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation, see Directive 2006/42/EC and ISO 12100, or
- § combination of the probability of occurrence of harm and the severity of that harm;
  harm means physical injury or damage to the health of people, or damage to property or the environment, see ISO/IEC Guide 51 and ISO 14971.

# The Elements of a standard (ISO/IEC Directives)




***But:***

**A requirement that the values of a characteristic be stated by the manufacturer instead of specifying the values themselves is not permissible in the case of health and safety requirements. [ISO/IEC Directives]**

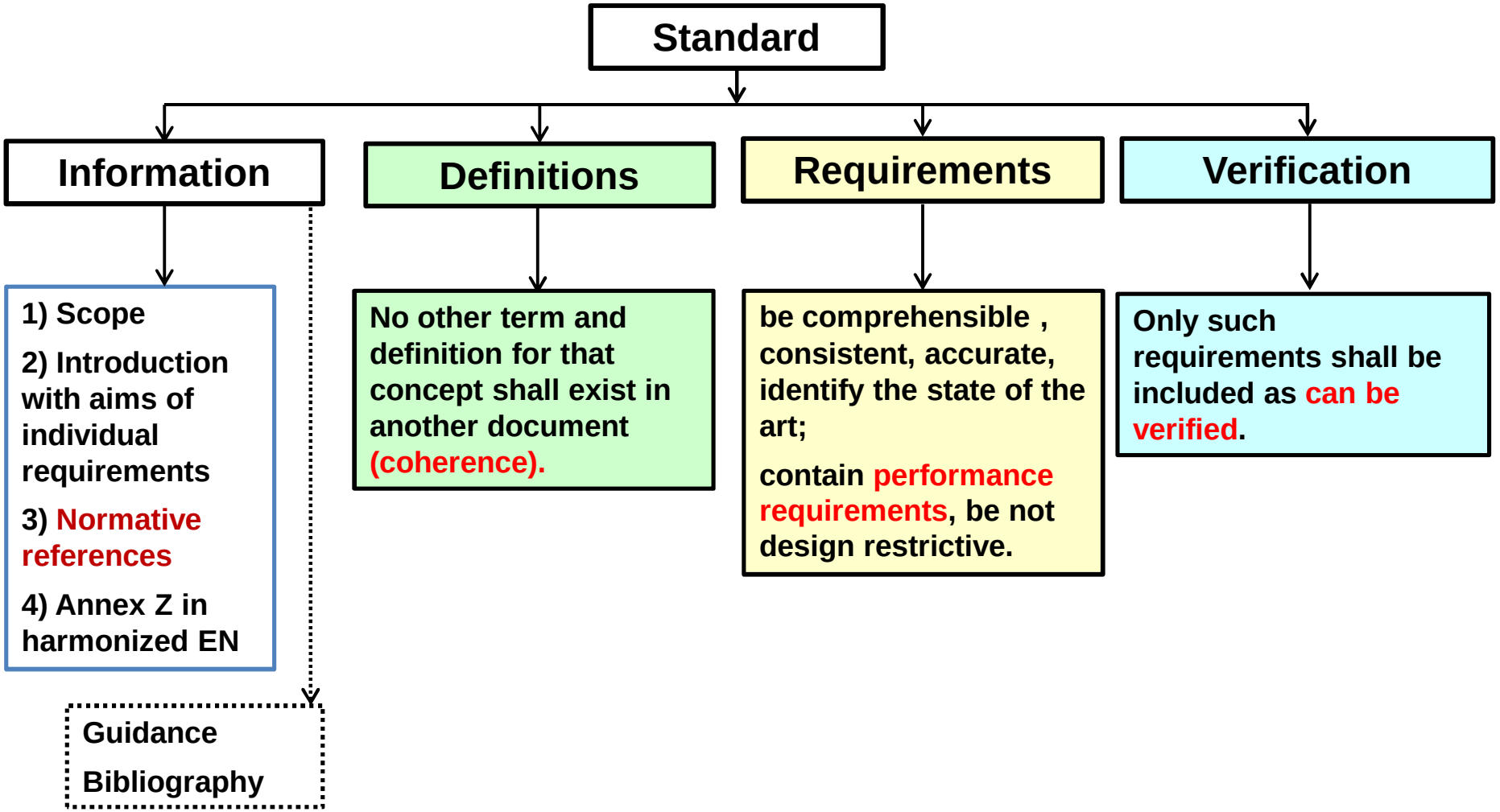
***Negative Example:***

***The minimum level of sterility assurance, SAL, to be achieved by the sterilization process on and/or within a product shall be specified.***
***[ISO 17665-1, 8.2]***

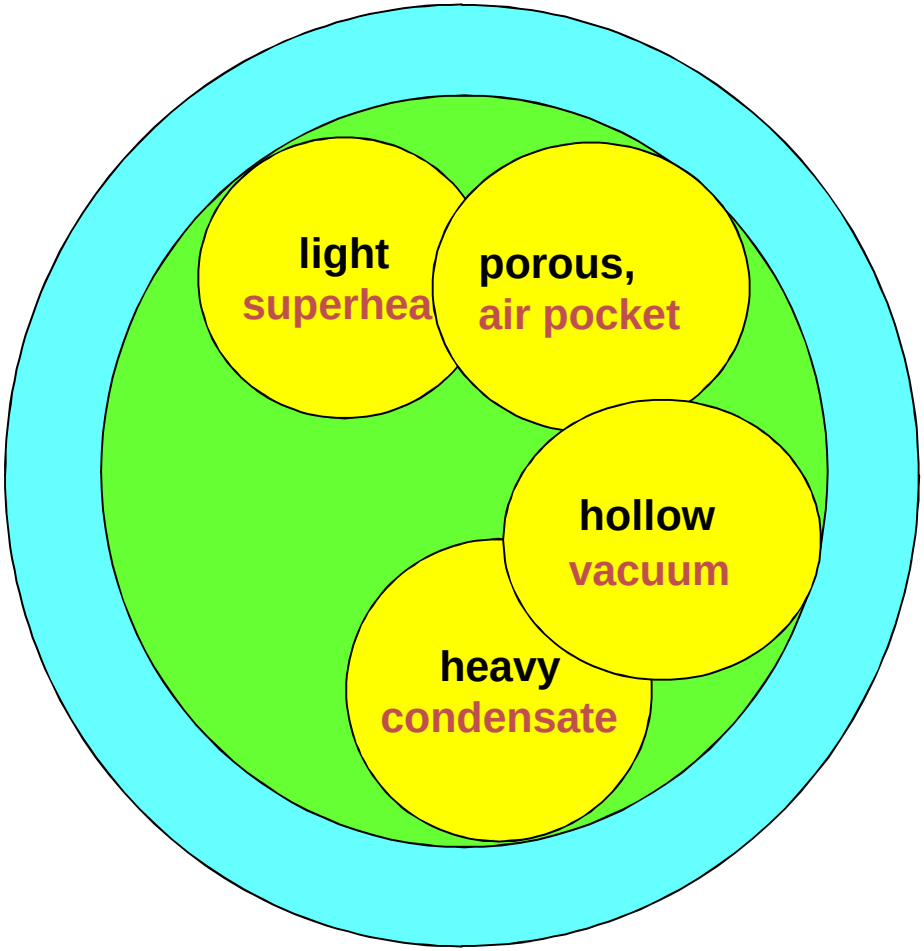
***Positive example***

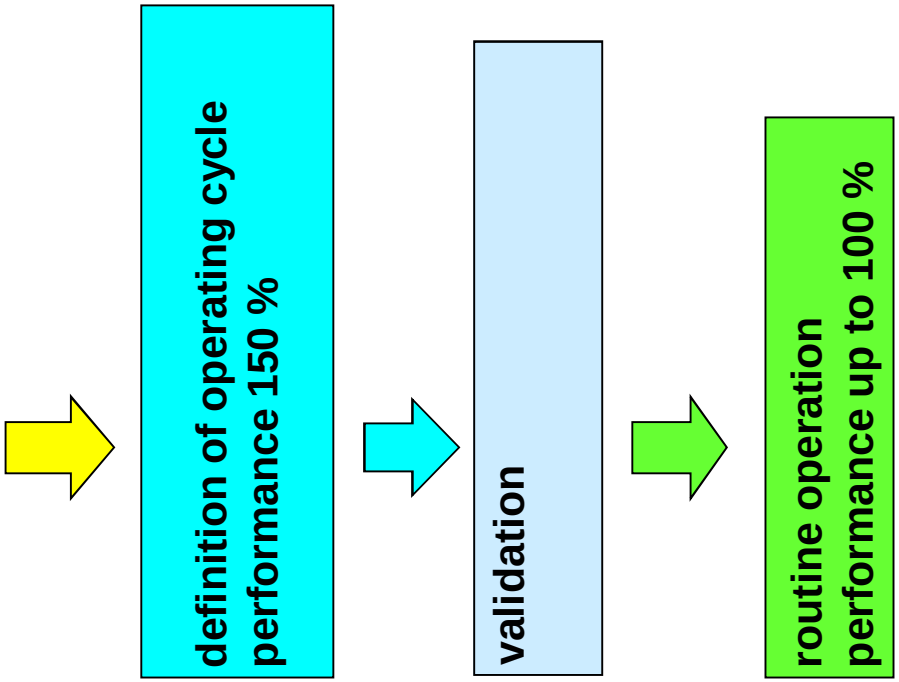
***The holding time shall be not less than 15 min, 10 min and 3 min for sterilization temperatures of 121 °C, 126 °C and 134 °C respectively.***
***[EN 285, 8.2.1.2.4 ]***

# The Elements of a standard (ISO/IEC Directives)

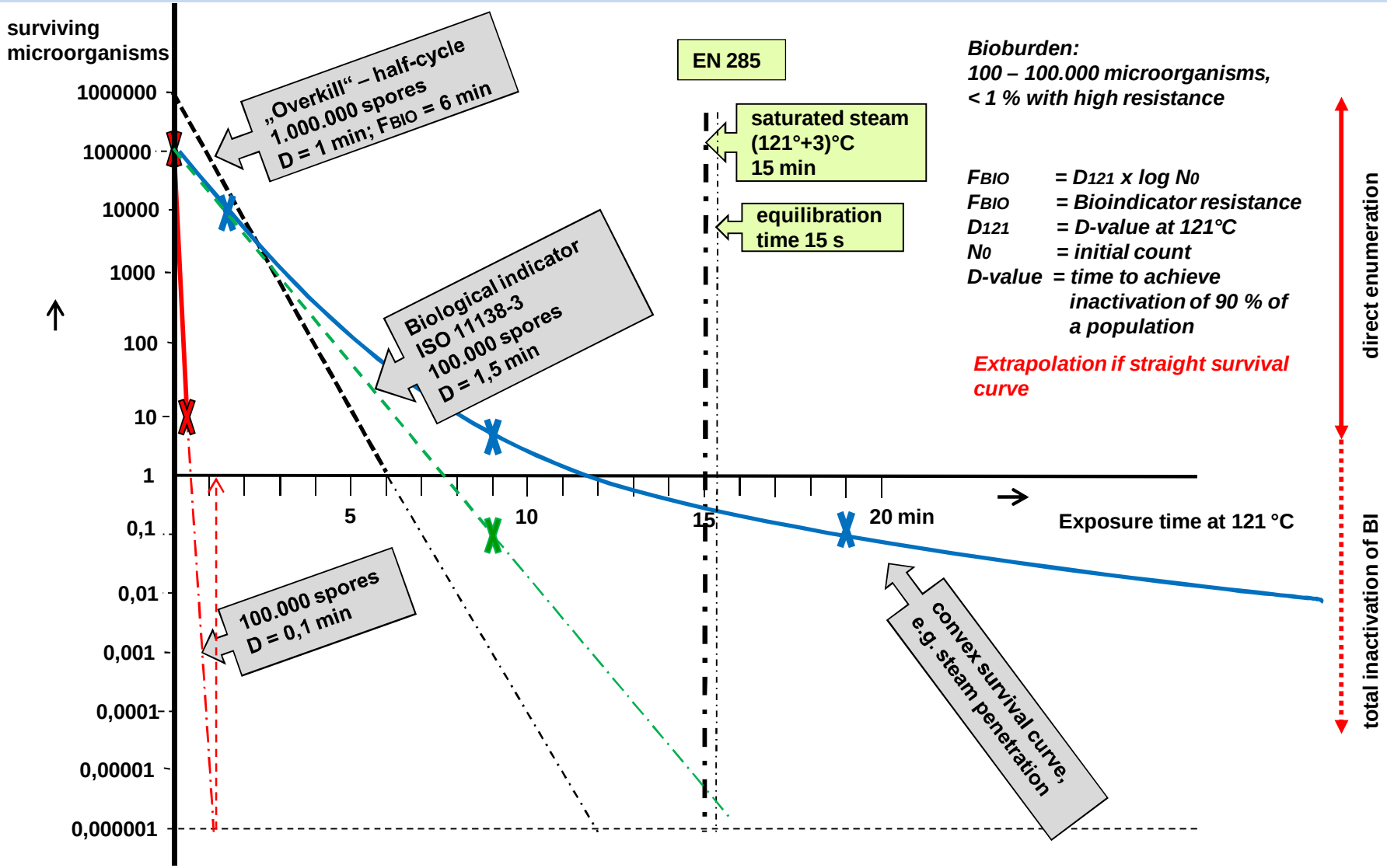


**Cycle design according to load characteristics**

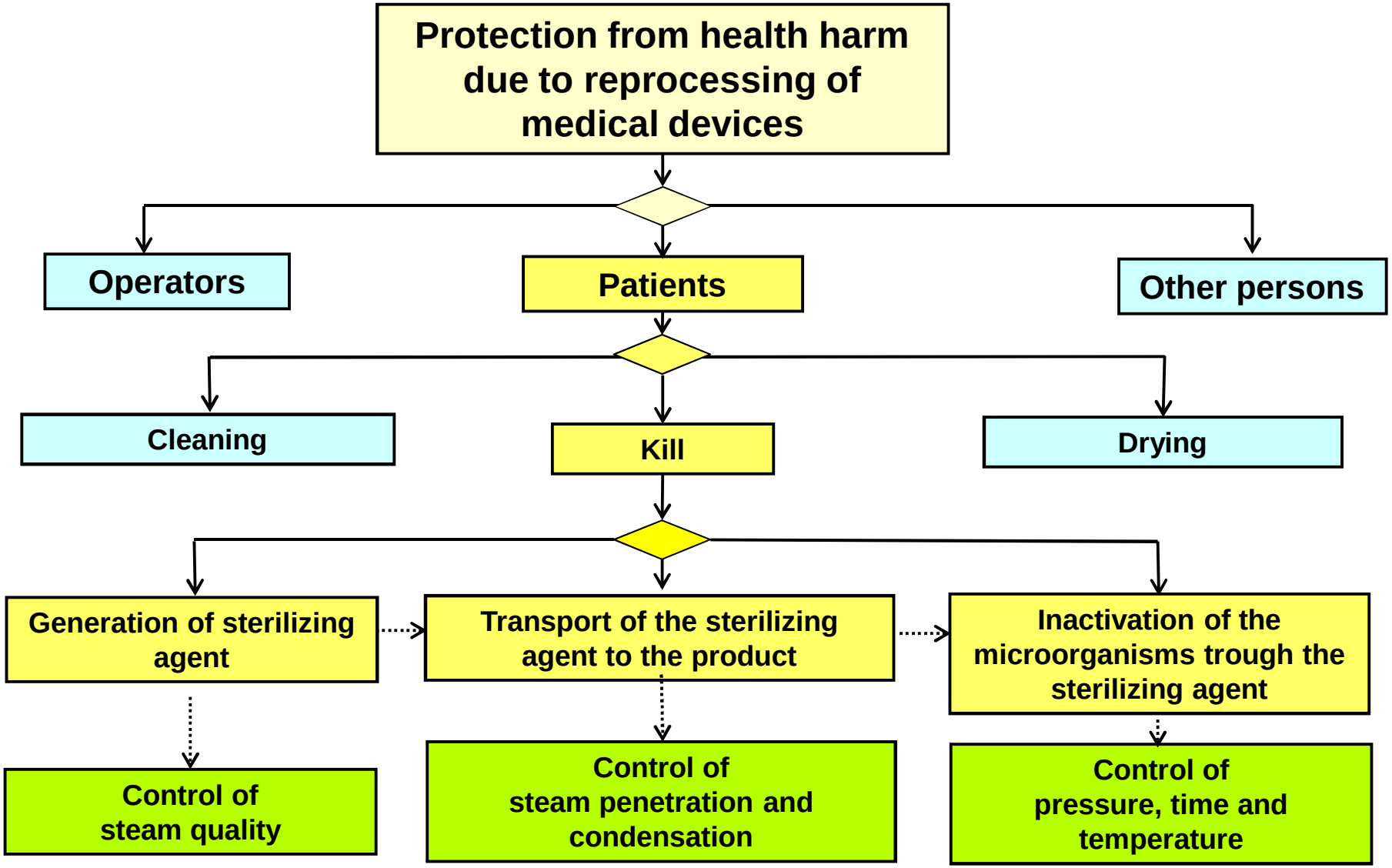


# Inactivation of biological indicators (ISO 14161)



# Purpose of sterilization in health care



# Reproducibility of sterilization in health care

| Control function | ISO 17665 | EN 285 |
|---|---|---|
| Steam quality | See EN 285 | Not normative,<br>criteria in 13.3, tests in 21 and 23, contaminants in Annexes B, D |
| Cycle parameters | | Required in 7 and 8, tests in 16 to 23 |
| Process parameters | See Pharmacopoeias | Requirements in 7, criteria in 8.2.1,<br>tests in 16 and 23 |
| Steam penetration | Required in 12.1.6<br><br>Indicator shall “comply with the applicable parts of the ISO 11140 series” | Required in 8.1 and 8.2.2<br>test in 16, 17, (resp. 15) and 23<br>Indicator according ISO 11140-3, ISO 11140-4 |
| Hollow | | Required in 8.2.5, tests in 15 |
| Light, superheat | Only “empty chamber” without criteria | Only “Antenna” in 8.1 and 8.2.1.2.2, test in 16 |
| Heavy, condensate | | |
| Fault recognition | See EN 285 | Required in 7.2, tests missing,<br>air detector in 8.2.4 (Option)<br>Tests in 20 and 23 |

**International standards support free trade.**

**European standards support legal requirements and free trade.**

**Users are not supported.**