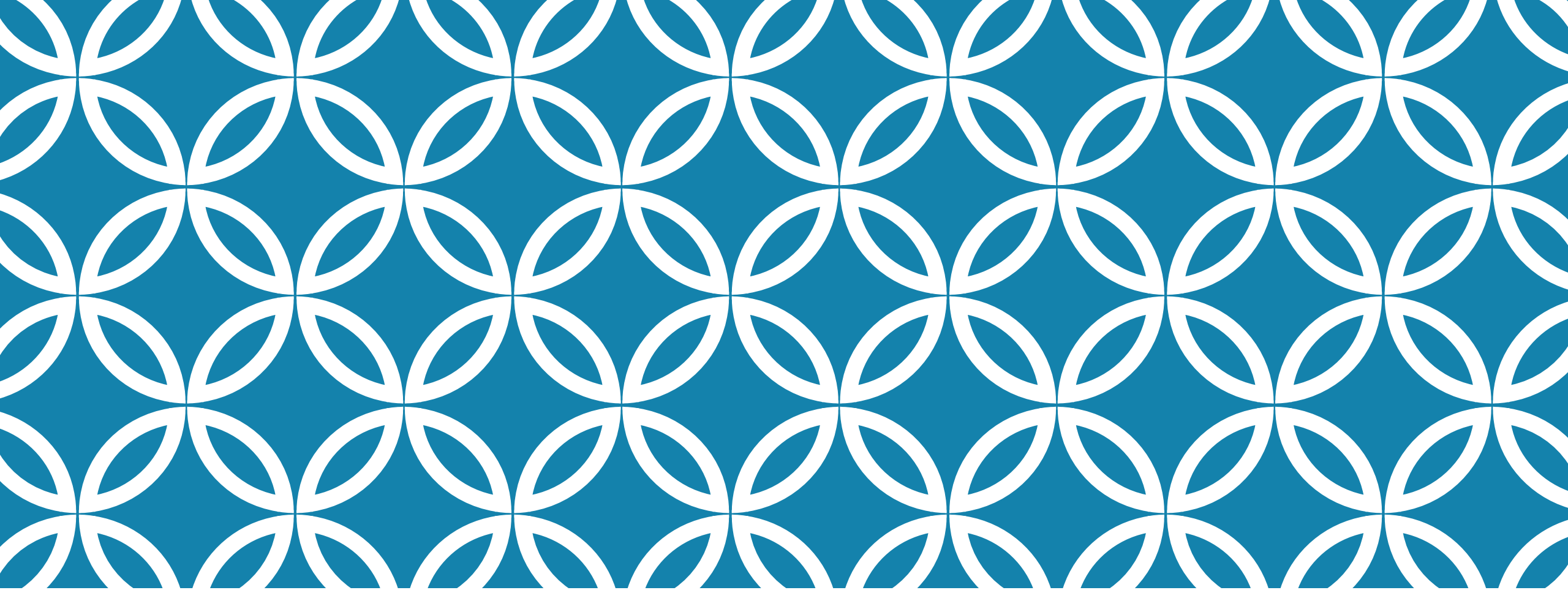


101 ASEPTIC: CRITICAL FACTORS

Ana Soares

CRITICAL FACTORS DEFINITION*:

Critical Factor* means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility

Critical factors specified in the scheduled process **shall** be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Such measurements and recordings should be done at regular intervals.

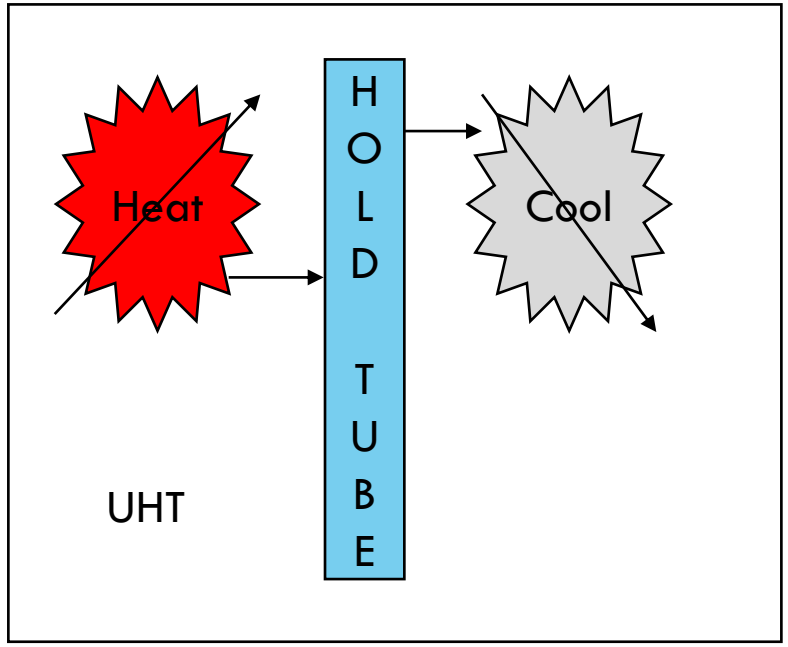
Scheduled process* means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of microorganisms of public health significance, and shall be at least equivalent to the process established by a competent processing authority to achieve commercial sterility.

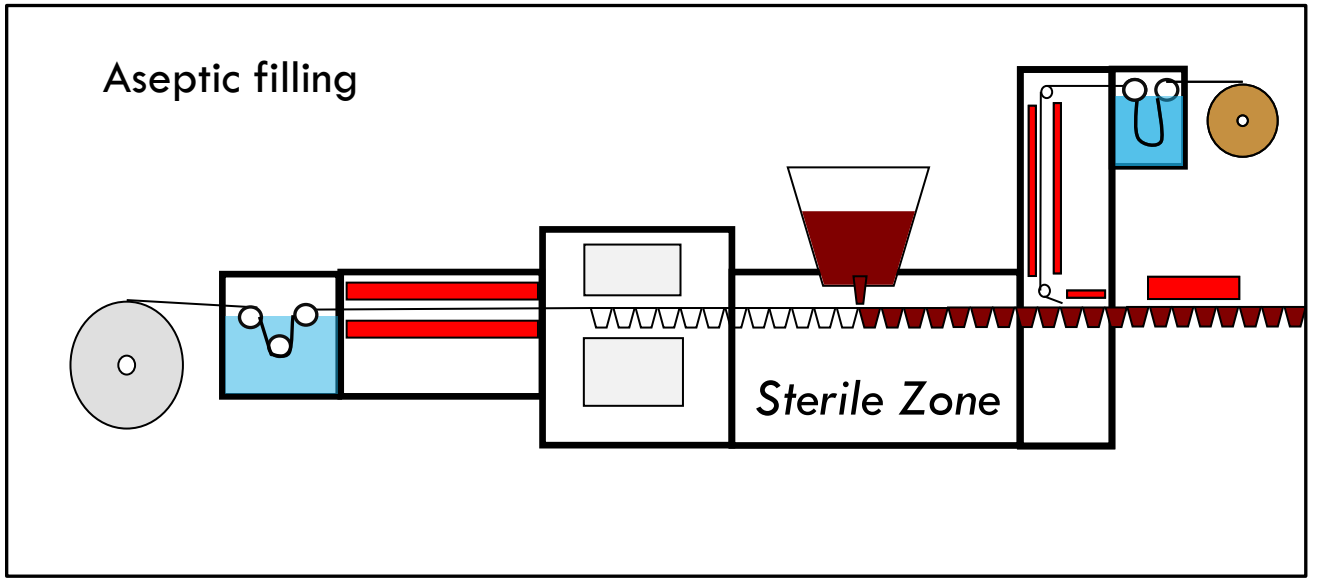
* According to CFR 21 part 113

Scheduled process** means all the conditions needed to achieve and maintain commercial sterility of equipment, containers and food.

** According to CODEX definition

ASEPTIC PROCESSING





AREAS OF CONSIDERATION:

1) PRE- STERILIZATION OF EQUIPMENT
2) PRODUCT STERILIZATION
3) STERILIZATION OF PACKAGING EQUIPMENT
4) MAINTENANCE OF STERILITY

1) PRE- STERILIZATION OF EQUIPMENT:

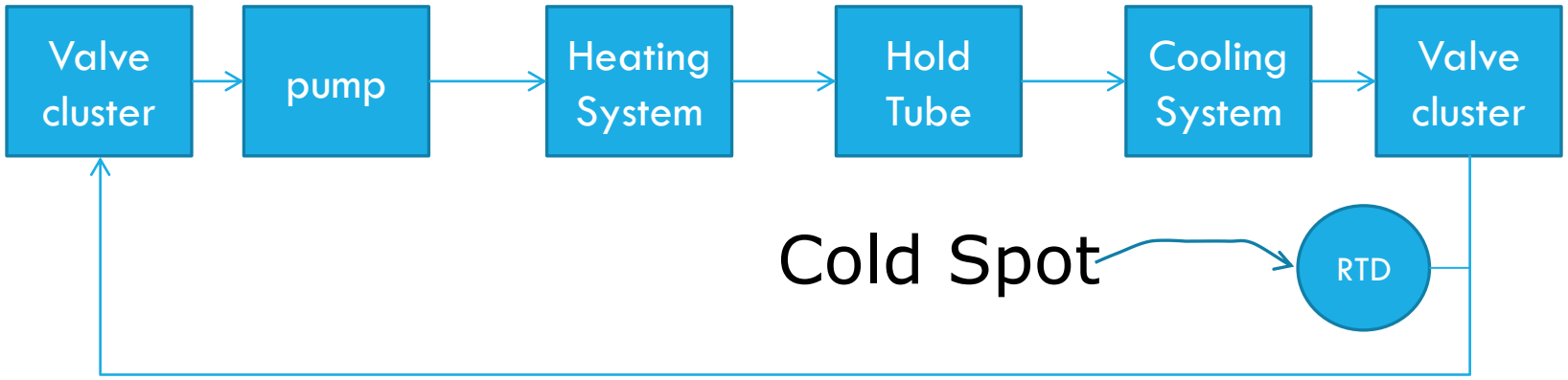
All the equipment used for sterilizing the product and after the hold tube needs to be brought to a condition of commercial sterility, often the line will be divided into smaller “cycles” that are to be sterilized, the different processes can be isolated (e.g.: hold tube and cooler/ surge tank/ filler).

- Minimum treatment is normally 250F/ 121C for 30mins
- Validation based on challenge test surrogate for C. *botulinum* (e.g.:G. *stearothermophilius*)

1) PRE- STERILIZATION OF EQUIPMENT:

Critical factors to be considered hold tube sterilization:

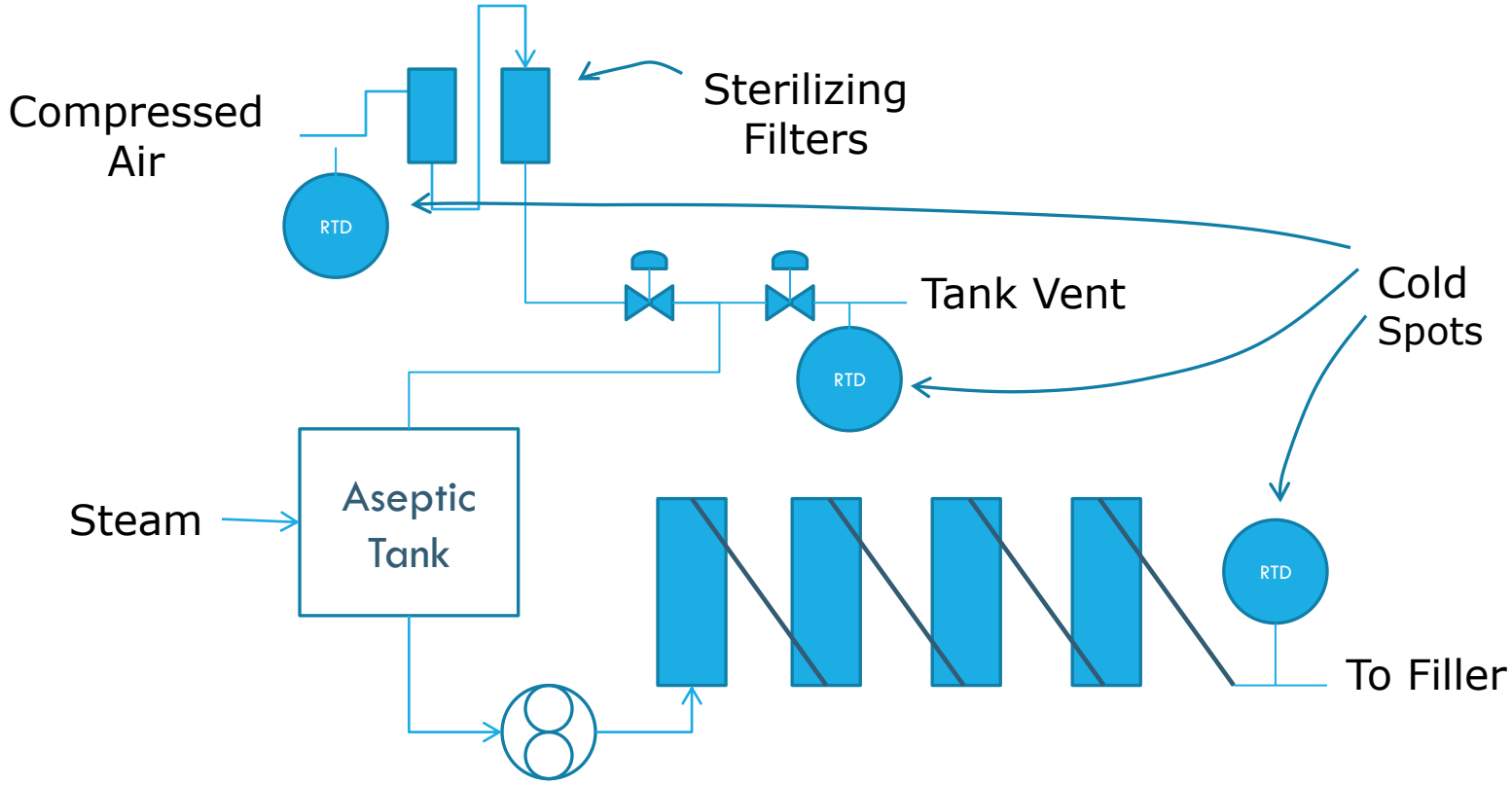
- Sterilizing medium (e.g.: water)
- Minimum sterilizing temperature (at the cold spot)
- Minimum sterilizing time (recirculation of sterilizing medium at the minimum temperature)
- Minimum backpressure



1) PRE- STERILIZATION OF EQUIPMENT:

Critical factors to be considered surge (or aseptic) tank sterilization:

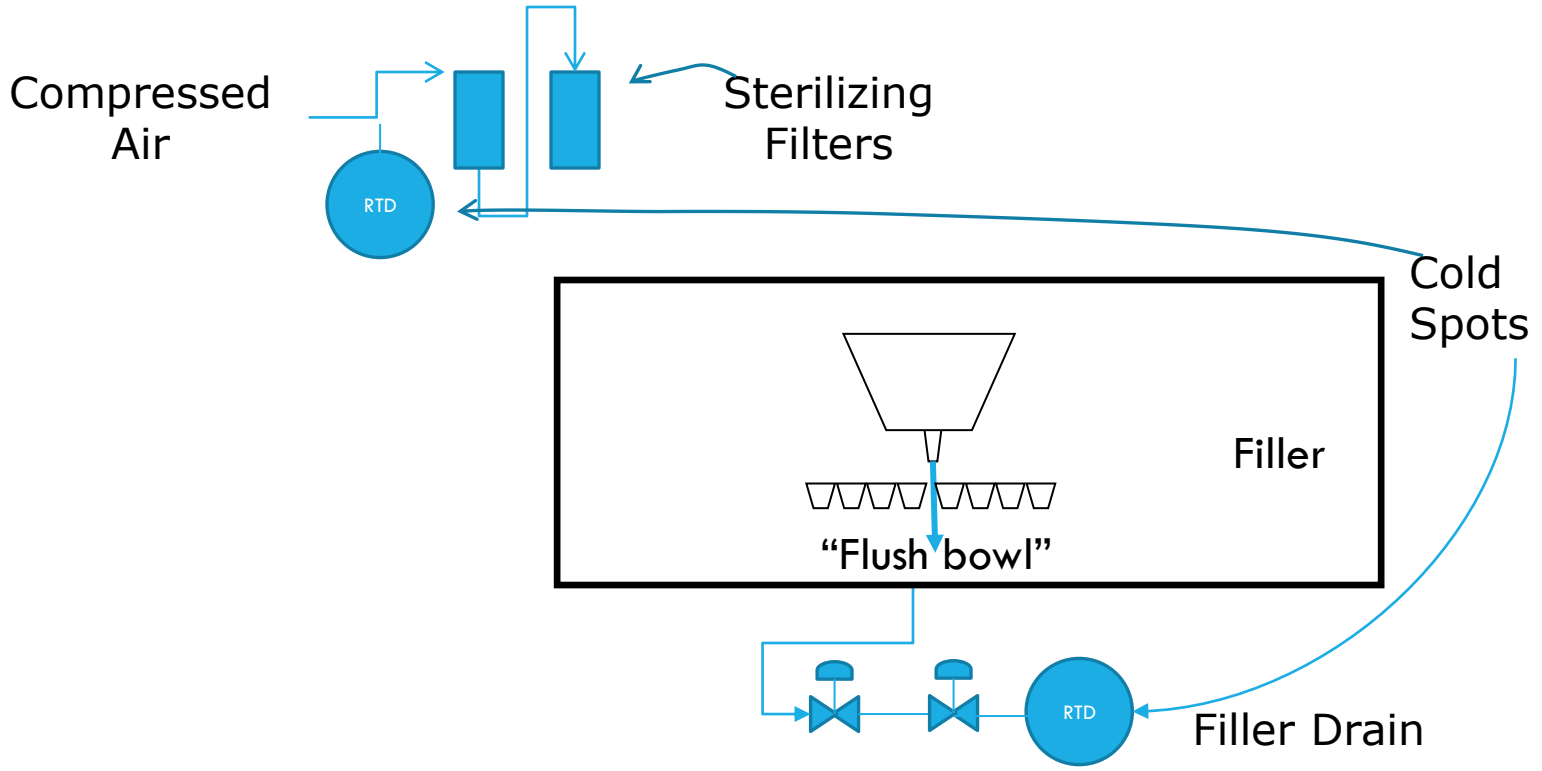
- Sterilizing medium (e.g.: water/ steam)
- Minimum sterilizing temperature (at the cold spot(s))
- Minimum sterilizing time (recirculation of sterilizing medium at the minimum temperature)
- Minimum overpressure



1) PRE- STERILIZATION OF EQUIPMENT:

Critical factors to be considered sterilization filler “filling”:

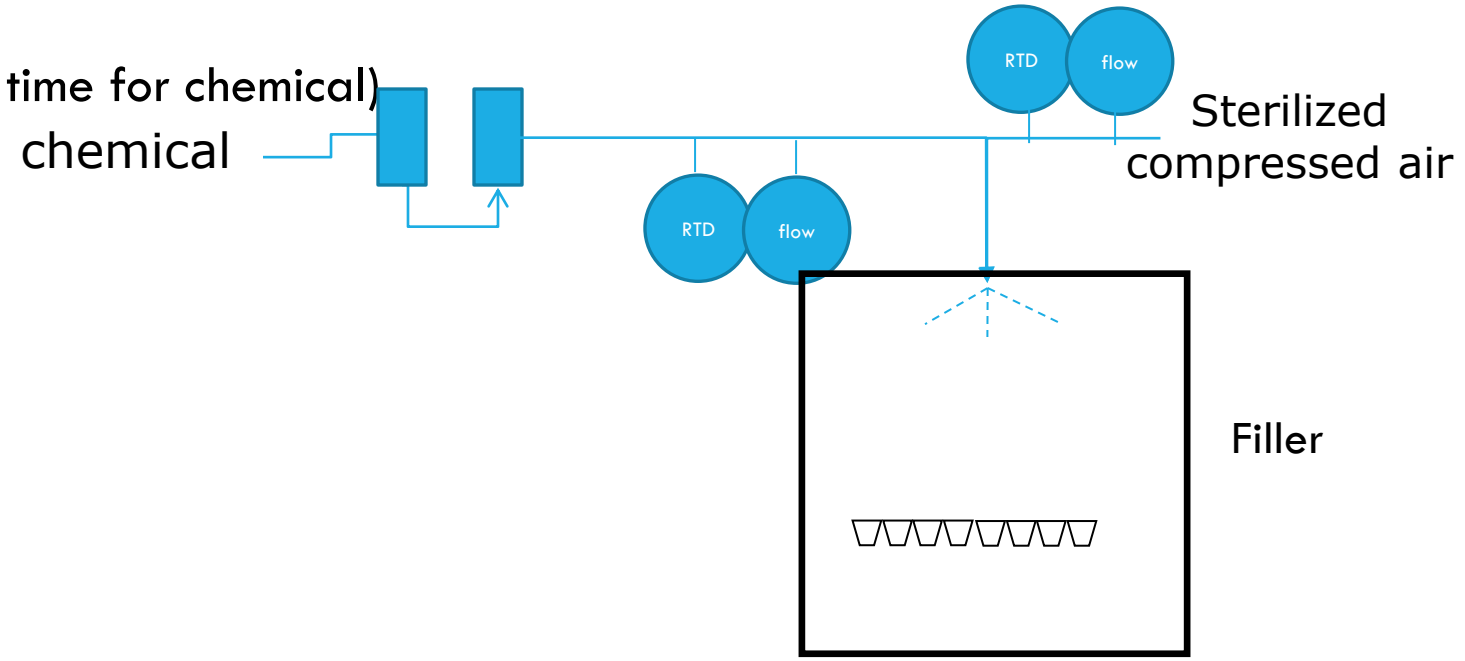
- Sterilizing medium (e.g.: water/ steam/ chemical)
- Minimum sterilizing medium concentration
- Minimum sterilizing temperature (at the cold spot(s))
- Minimum sterilizing time (recirculation of sterilizing medium at the right conditions)
- Minimum overpressure



1) PRE- STERILIZATION OF EQUIPMENT:

Critical factors to be considered sterilization filler tunnel:

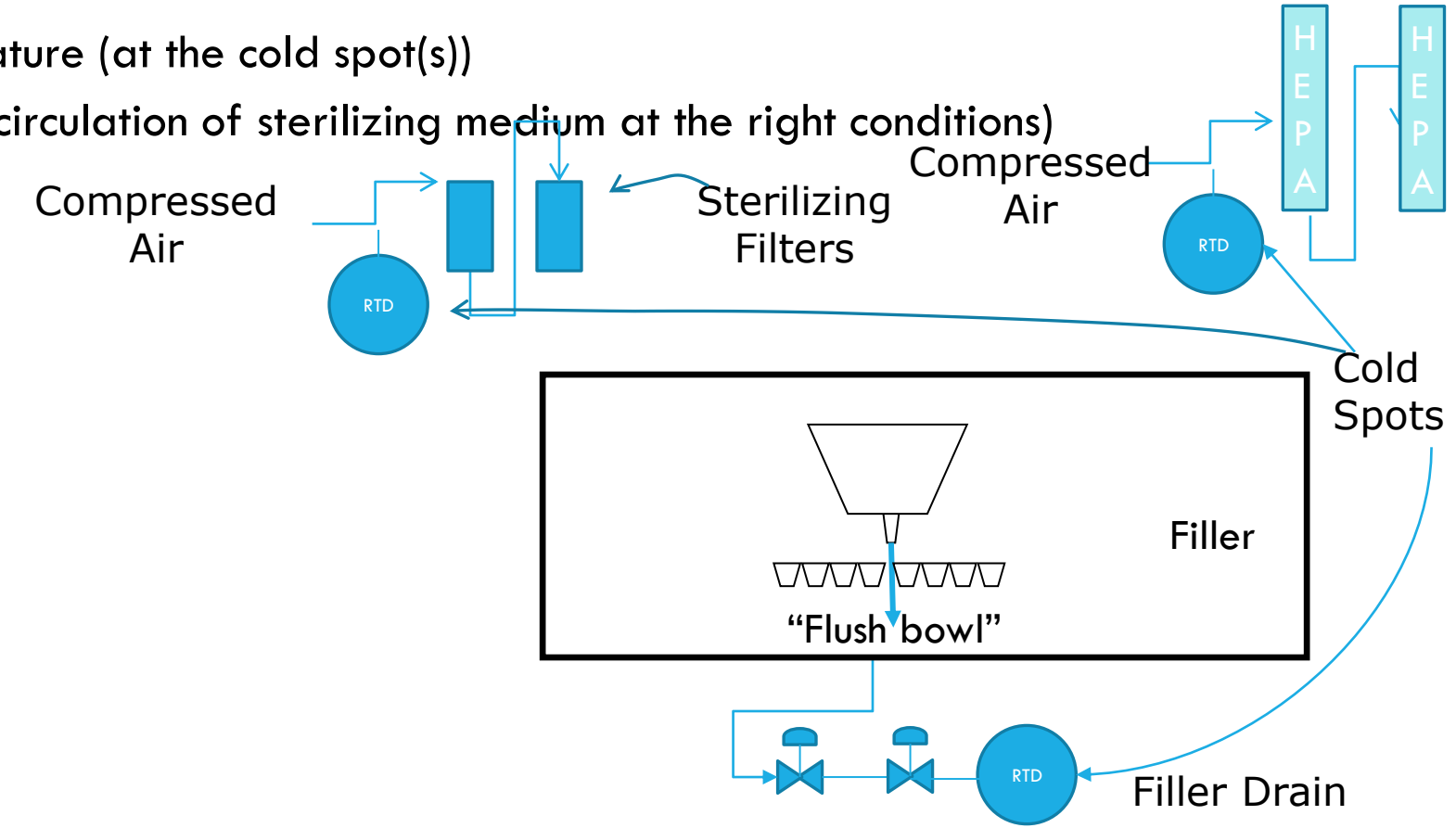
- Pre-heating of the tunnel
- Sterilizing medium (e.g.: steam/ chemical)
- Minimum sterilizing medium concentration
- Minimum sterilizing medium quantity (e.g.: measurement of spray quantity or air amount)
- Minimum sterilizing temperature
- Minimum sterilizing time (contact time for chemical)



1) PRE- STERILIZATION OF EQUIPMENT:

Critical factors to be considered sterilization filler sterile air and over pressure:

- Sterilizing medium (e.g.: steam/ chemical)
- Minimum sterilizing medium concentration
- Minimum quantity/ volume
- Minimum sterilizing temperature (at the cold spot(s))
- Minimum sterilizing time (recirculation of sterilizing medium at the right conditions)
- Minimum overpressure



2) PRODUCT STERILIZATION

Critical factors to be considered for pre-treatments:

- Parameters for mixing of specific ingredients (hydration/ mixing of starches)

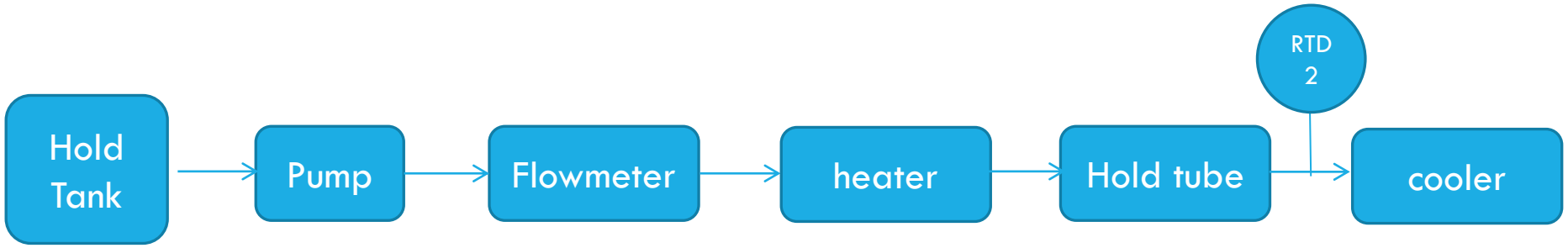
Critical factors to be considered product properties:

- Particulates (maximum % and sizes)
- pH
- Total solids
- Viscosity/ density

2) PRODUCT STERILIZATION

Critical factors to be considered for hold tube:

- Minimum lethality for commercial sterility of product
- Minimum Temperature hold tube outlet (indicator/ recorder)
- Minimum residence time/ Maximum flow (flow meter)
- Hold tube: length/ diameter/ flow correction factor (turbulent or laminar- Reynolds number calculation)
- Minimum backpressure
- *In cases of direct heating systems pre-heating temperature*
- Product to product regenerators- higher pressure on the treated side



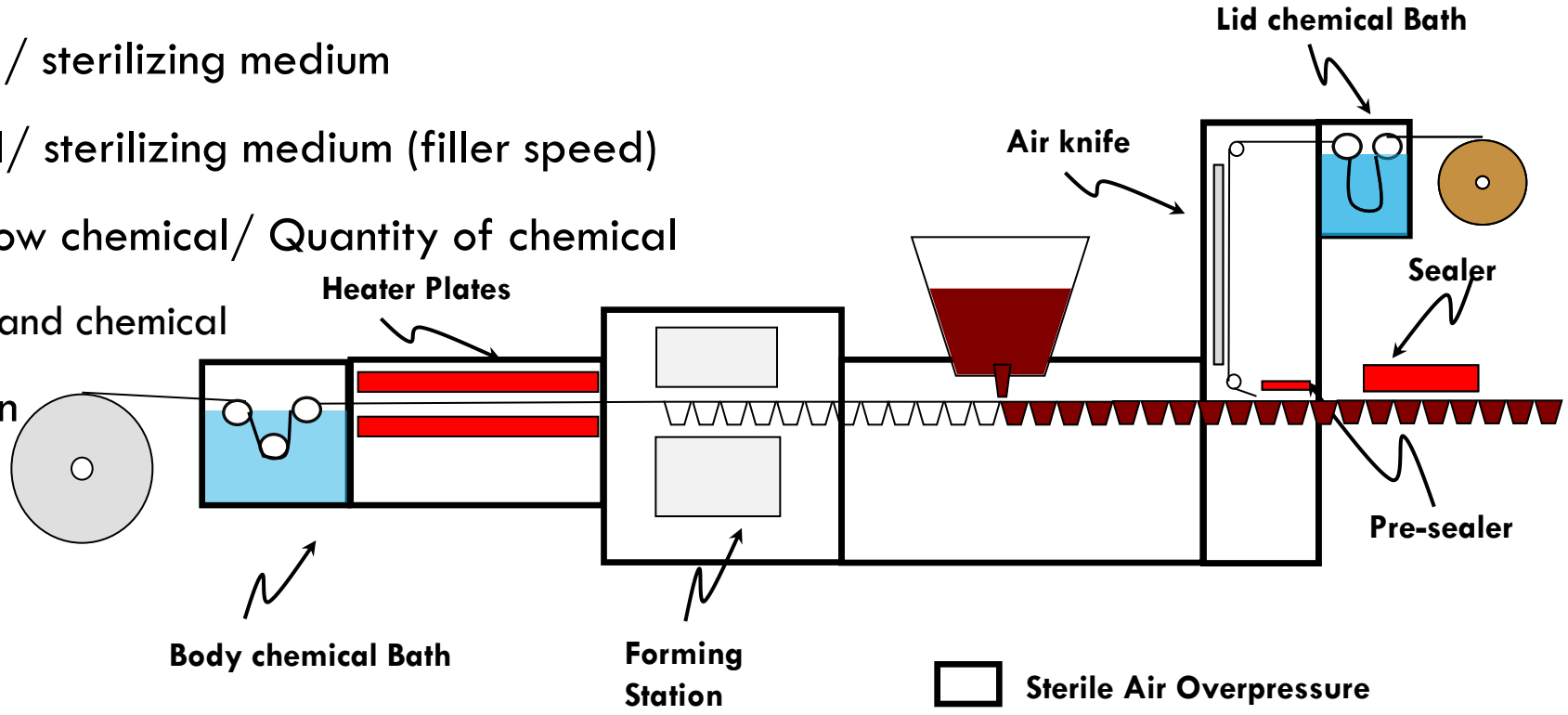
3) PACKAGE STERILIZATION

Critical factors to be considered sterilization of packaging materials (are specific to a pack):

- Sterilization media
- Chemical concentration minimum
- Phase characteristics sterilizing medium (e.g. vapor/spray/ liquid)
- Temperature of chemical/ sterilizing medium
- Contact time on chemical/ sterilizing medium (filler speed)
- Chemical bath levels/ Flow chemical/ Quantity of chemical

When sprayed quantity of air and chemical

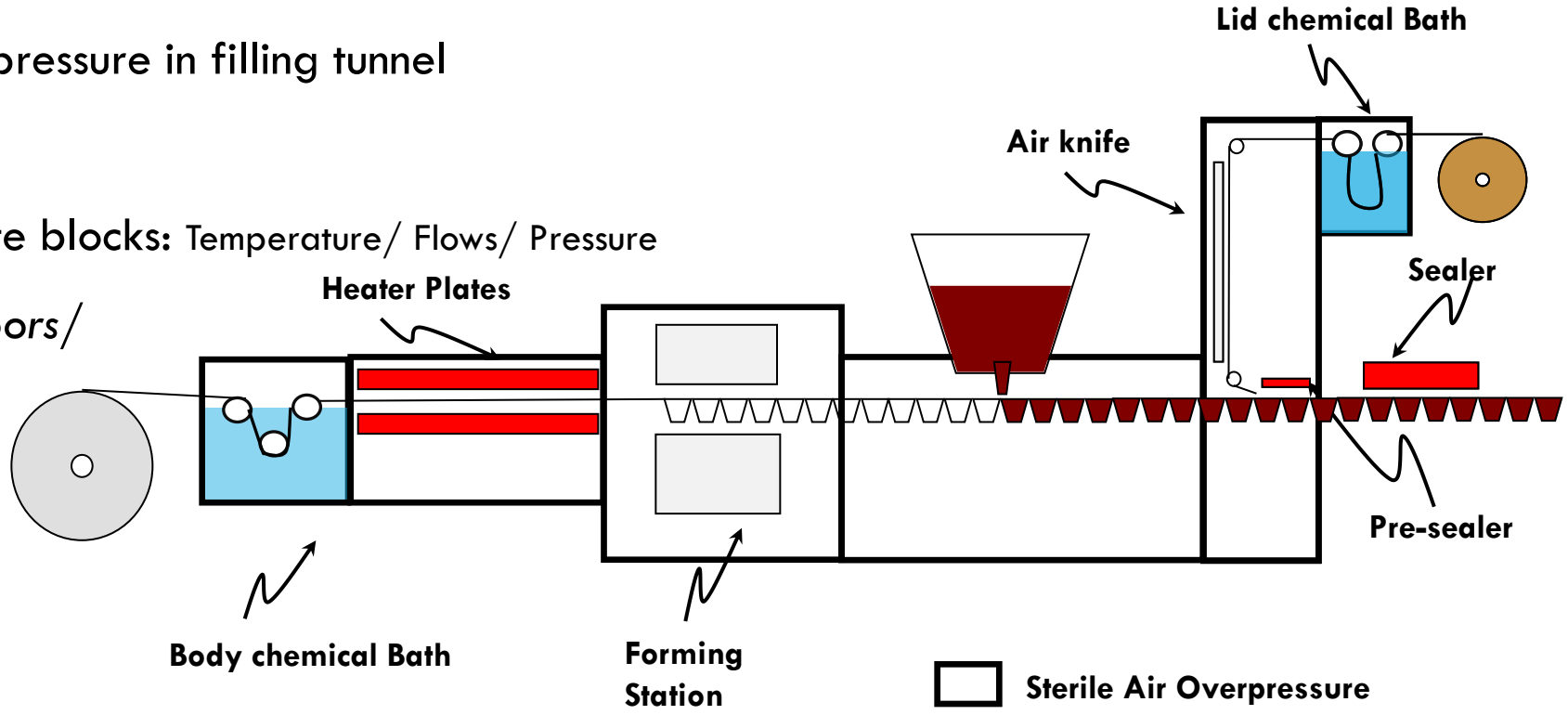
- "depending on validation conditions heater plates"
- Air knife temperature



4) MAINTAINING STERILITY

Critical factors to be considered for maintenance of sterility:

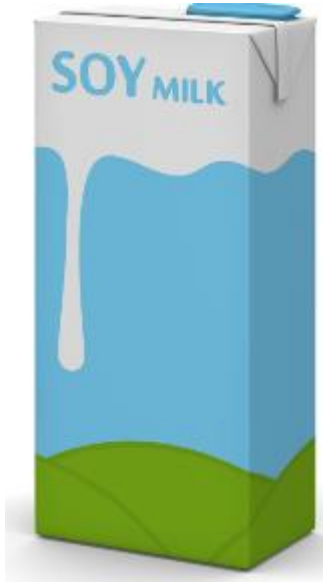
- Air incinerator (temperatures/ flows)
- Minimum sterile air overpressure required for aseptic tank (min 1PSI)
- Minimum sterile air overpressure required for filler bowl
- Minimum sterile air overpressure in filling tunnel
- **Seal integrity**
- Steam or cold condensate blocks: Temperature/ Flows/ Pressure
- *Physical barriers (e.g.: doors/ windows/ chemical curtains)*



4) MAINTAINING STERILITY

Critical factors to be considered for seal integrity:

- Pressure of sealing plate
- Temperature of sealing plate
- Longitudinal/ transversal seal
- Bottles- torque
- Form Fill Seal Bag seals: pressure/ temperature



THANK YOU FOR LISTENING!
ANY QUESTIONS?