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Sterile inks and methods of sterilization

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infectious diseases probably rare

- step-up of professional tattoo studios
- adoption of safety measures
- good quality

this technique is not devoid of potential adverse effects

cases of cutaneous and systemic infectious complications following tattooing

difficult to determine the true incidence of tattoo-related infections :
late retrospective investigation

BACTERIA

S. pyogenes

methicillin-resistant *S. aureus*

P. aeruginosa

non-tuberculous mycobacteria

VIRUS

human papilloma virus

molluscum contagiosum

MOULDS

T. rubrum
E. floccosum

ResAP(2003)2

warranty of sterility, no preservatives, appropriate hygienic conditions

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- they do not contain preservatives;
- <u>they are sterile</u> and supplied in a container which maintains the sterility of the product until application;
- they are supplied in a packaging size appropriate for single use on an individual consumer

inks must meet the provisions for labeling and classification that apply to all chemicals according to the EU Regulation 1272/2008 and meet the requirements ofItalian Codex for Consumer Safety reorganized all the European regulations for the safety of the consumer

ResAP(2008)1

warranty of sterility, preservatives, appropriate hygienic conditions, multi-use containers

……

- <u>they are sterile</u> and supplied in a container which maintains the sterility of the product until application, preferably in a packaging size appropriate for single use. *In case multi-use containers are used, their design should ensure that the contents will not be contaminated during the period of use;*
- *preservatives should only be used to ensure the preservation of the product after opening and by no means as a correction of insufficient microbiologic purity* in the course of manufacture and of inadequate hygiene in tattooing and PMU practice

sterile product : free from viable microorganisms

Items produced under controlled manufacturing conditions have microorganisms, by definition, non-sterile

The purpose of sterilization processing is to destroy the microbiological contaminations on these non-sterile products.

STERILIZATION
eliminates, removes, kills, all forms of life and other biological agents present in a specified region

Sterility: through various means
heat, chemicals, high pressure, filtration, irradiation

the sterilization must not alter the organoleptic, physical and chemical characteristics

both **beta (β) and gamma (γ) radiation**

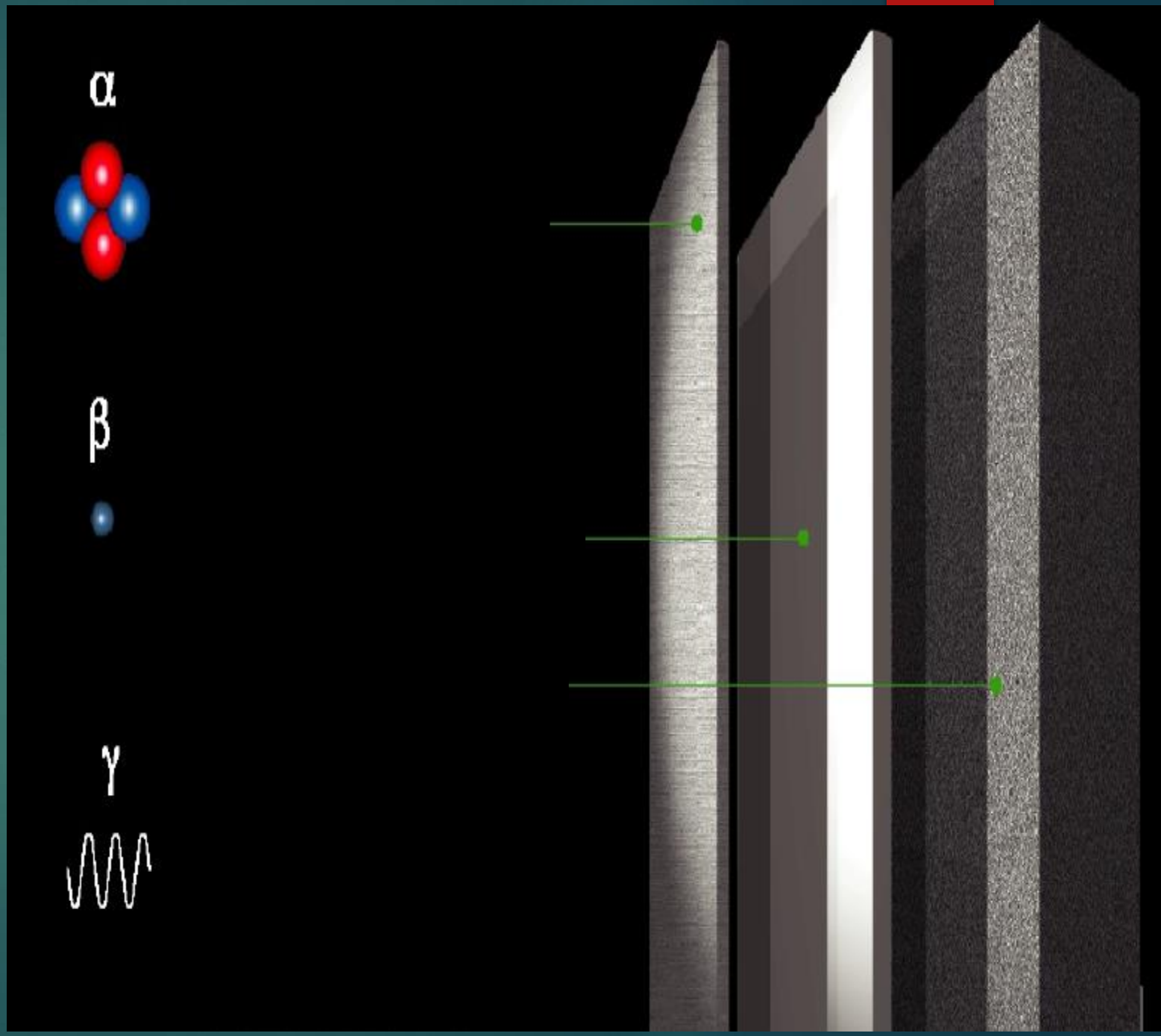
sterilization of the final packaged product

Attention to : the microbiological barrier properties of the packaging, the control of the environment in which the product is manufactured, packaged and stored

difference β **and** γ **radiations:** material penetration and dose rates

- ✓ beta rays (β): high dose rate and limited penetration depth
- ✓ gamma rays (γ): high penetration capability and relatively low dose rate

Tattoo inks : sterilization at a dose level greater than 25 kGy



Irradiation doses : in gray (Gy)

Gy is measured in joule/kg absorbed energy

$$1\ Gy = 1 \quad = 1\ m^2 \times s^{-2}$$

γ rays : energy as electromagnetic radiation emitted by an radioisotope, Cobalt-60 or Caesium-137

Applied dose = energy source $\times$ time exposed

Higher doses of radiation, greater destruction of microorganisms

radiation provokes structural defects in microbial DNA, which, unless repaired, are likely to inhibit DNA synthesis

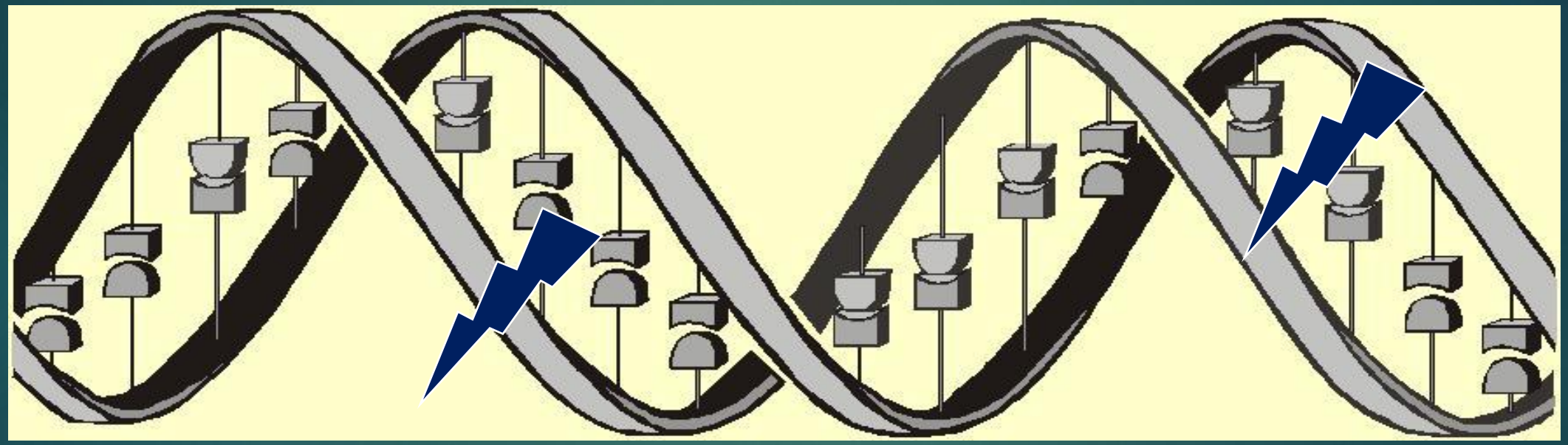
Radiation resistance: differences in chemical and physical bacterial structure, as well as ability to recover from radiation injury

Cell susceptibility

mammals > insects > vegetative forms > viruses >sporal forms

Cells are capable of repairing many of the different DNA breaks

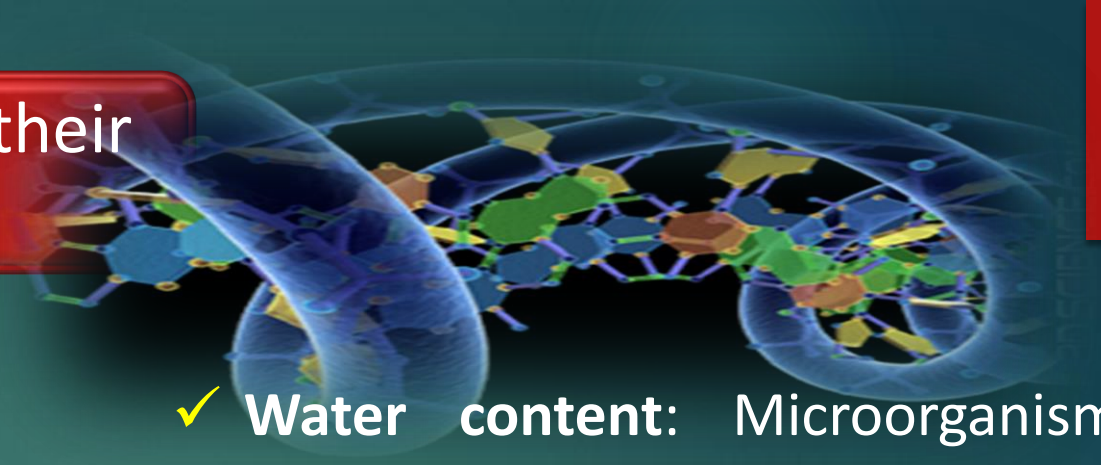
radiation induced lesions in DNA



Single-strand breaks

Double strand breaks

microorganisms differ greatly in their resistance to radiation



resistance to radiation depends on:

- ✓ **Nature and concentration** of the bioburden
- ✓ **Nature and amount** of damage in DNA
- ✓ **Number, nature and longevity** of radiation
- ✓ **Anaerobic condition** (absence of oxigen)
- ✓ **Water content**: Microorganisms are most resistant when irradiated in dry conditions.
- ✓ **Temperature**: Treatment at elevated temperature, generally above 45°C, synergistically enhances the bactericidal effects
- ✓ **Composition of the medium**: surrounding cell

Cell form and state of DNA in the cell is important in relation to bacterial inactivation

- ✓ Generally, bacterial spores are considered more radiation resistant than vegetative bacteria
- ✓ Among vegetative bacteria, gram-positive bacteria are more resistant than gram-negative bacteria
- ✓ Vegetative cocci are more resistant than vegetative bacilli
- ✓ Yeasts and moulds are more resistant to radiation than vegetative bacteria

Microbiological contamination of sealed or in use tattoo inks (data from Europe and USA)

> 3800	11% (S+U)	**mostly *Bacillus* and gram +**
> 800	20% (S+U)	
> 350	34% (S)	
58	10% (S)	
34	66% (S+U)	
70	16% (S)	

The radiation sterilization process is considered highly effective

It is recognized that the sterility of an individual item in a population of sterilized products cannot be ensured in the absolute sense

Sterility Assurance Level (SAL) because

the sterility of a product can be defined

only in terms of **probability**

SAL : the probability that products sterilized in their final containers have a SAL of not more than one unsterile article per 1 million of items processed

The probability of microbial survival is a function of a series of factors, e.g. the number and species of microorganisms present in the product

radiation for tattoo inks sterilization

Advantages:

- ability to destroy contaminating microorganisms preserving their properties and characteristics
- No residues or radioactivity remain in the products

In light of the data reported in literature, the sterility process needs a well-planned quality control to ensure that irradiation reaches the inner part of the product, kill microorganisms and prevent their ability to recover from radiation injury

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