Sustainable Competence
in Advancing Healthcare

TRAINING COURSE ON SAFETY IN BRACHYTHERAPY

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Vienna, Austria

SAFETY INITIATIVES

FROM A MANUFACTURING STANDPOINT

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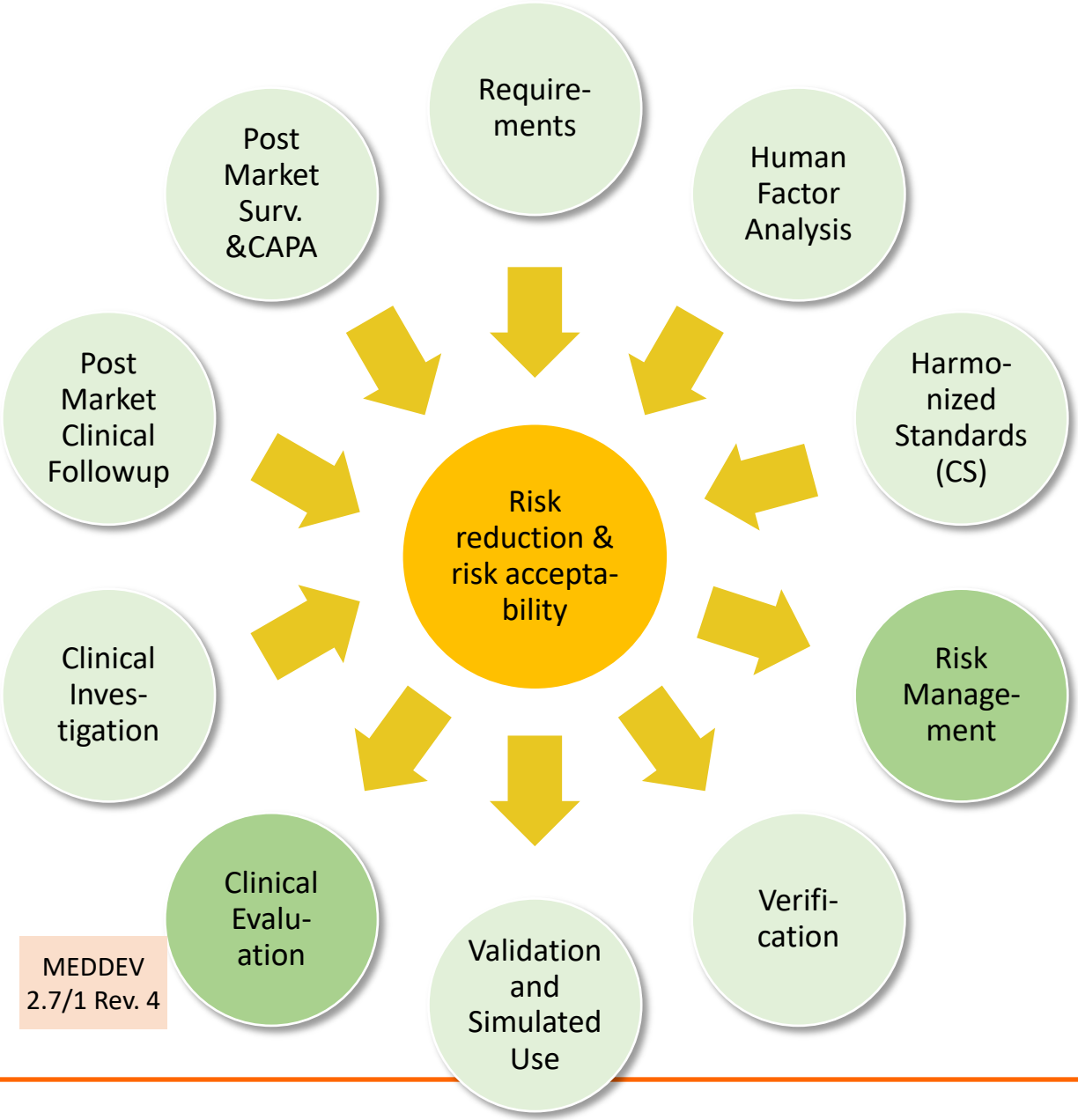
SAFETY ASPECTS

Improving safety further through:

- Continuous product improvement
- Better integrated solutions (TPS, OIS, RAL) to further avoid use errors
- Advance Dicom standards for brachytherapy
- Innovation: integrate therapy with live imaging and dose measurement, dose evaluation/summation
- More focus on QA aspects (tools, software)
- Prepare for future regulations and standards

RISKS AND BENEFIT ANALYSIS

- With the new Medical Device Regulation becoming effective in 2017, there is more focus on risk-benefit analysis and clinical evaluation
- COCIR is actively involved in discussions with the European Comission regarding the impact of this and other regulations on radiotherapy



ISO 14971: 2012

MEDDEV 2.7/1 Rev. 4

MDR art 2.15(e)
'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

Require-ments

Human Factor Analysis

Harmo-nized Standards (CS)

Risk Manage-ment

Risks

Verifi-cation

Vali-dation / Simulated Use

Clinical Evalu-ation

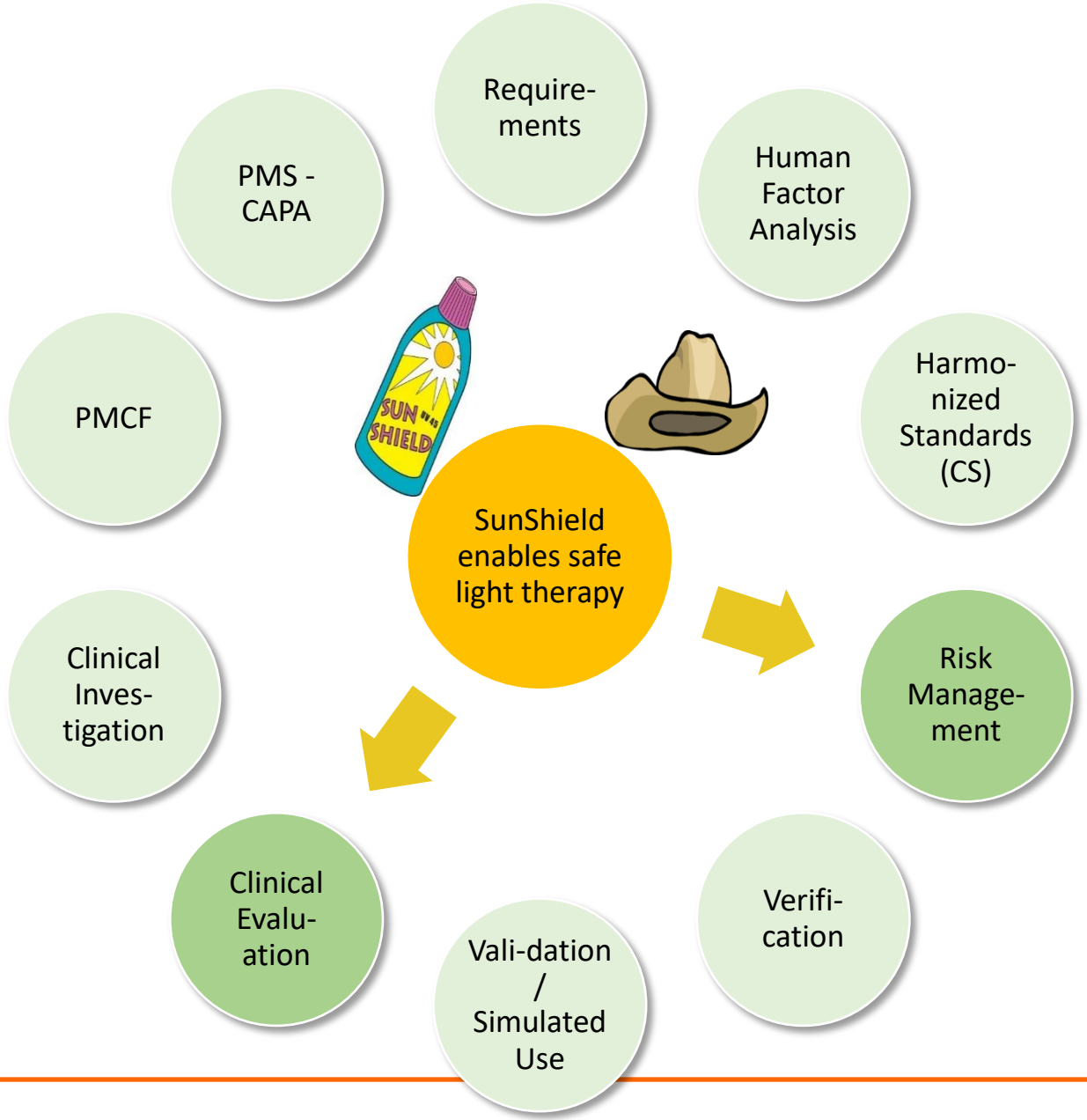
Benefits

Benefits outweigh the risks

Clinical Inves-tigation

PMCF

PMS - CAPA


Require-ments
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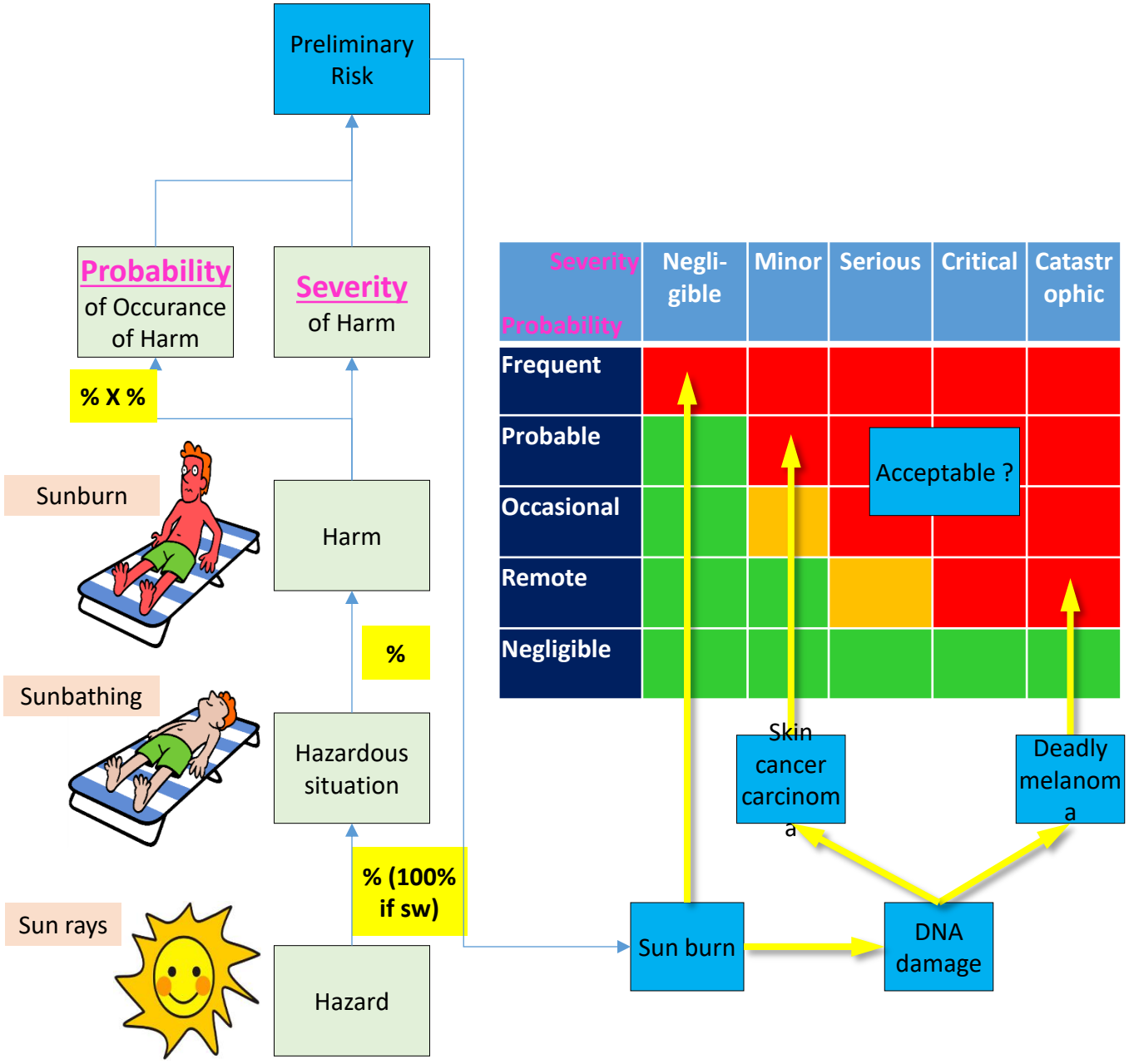
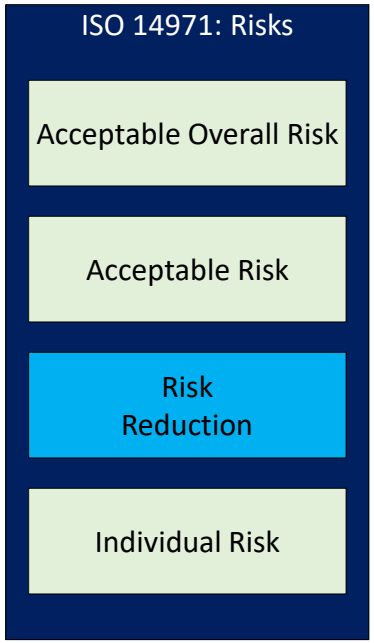
SUN SHIELD
SunShield enables safe light therapy


Preliminary Risk
Probability of Occurance of Harm
Severity of Harm
% X %
Sunburn
Harm
%
Sunbathing
Hazardous situation
% (100% if sw)
Sun rays
Hazard
Severity
Probability
Negli-gible
Minor
Serious
Critical
Catastr ophic
Frequent
Probable
Occasional
Remote
Negligible
Acceptable ?
Skin cancer carcinom a
Deadly melanom a
Sun burn
DNA damage



(GPRS 1, 2, 5 / ISO 14971 / ISO 62366)

Reduce foreseeable risk, use error and undesirable side-effects **as far as possible** & meet **State of the Art**:

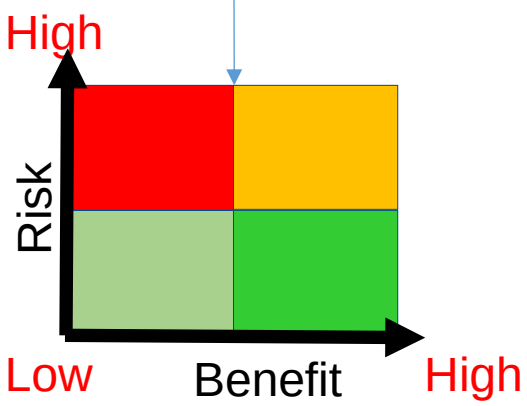
1. by safe design and manufacture
2. protection measures, including alarms
3. provide information for safety (warnings/precautions/contraindications) and training to users.

Evaluate effectiveness of **risk control** measures.

Assure risk control **traceability**.

Clinical Evaluation

Benefit-risk determination



Vitamin D:

* Reduces Risk of Cancer
* Lowers Inflammation
* Boosts Immune Function
* Regulates 2,00+ Genes
* Reverses Depression
* Lowers Blood Pressure
* Optimizes Body Weight
* Prevents Bone Loss
* Helps with MS and Autism

Clinical Evaluation: Benefits

- Improved clinical outcome
- Improved Quality of Life
- Improved Diagnosis
- Improved public health impact

Require-ments

PMS - CAPA

Human Factor Analysis

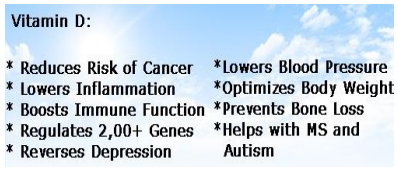
PMCF

Harmo-nized Standards (CS)

Benefits/ Risks Determin ation

Clinical Inves-tigation

Acceptable Risk



CE: Benefits

Vali-dation / Simulated Use

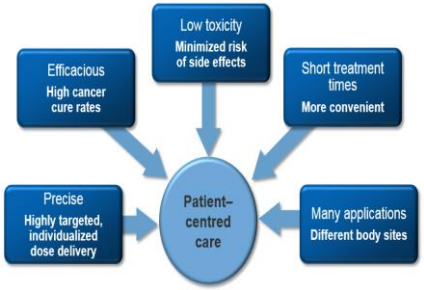
Verifi-cation

CONTROL OF SOURCE LOGISTICS

- Transportation of radioactive material is heavily regulated and has to comply with IAEA standards, Hass directive, IATA regulations, etc.
- Storage and security procedures at the hospital are less consistently regulated, as are licenses, e.g. activity limits
- Further improve source logistics, turnaround time
- Secure source supply and manufacturing (reactor)

GROW BRACHYTHERAPY

- Promote brachytherapy to the medical profession and patients for its efficacy, accuracy, minimal side effects, efficiency
- Promote brachytherapy to ministries, health insurance agencies, buying groups as a healthy investment
- Ensure continuity (source delivery, equipment, support, consumables) by adherence to quality standards and regulations



This is only possible when manufacturers, regulators and users work together to keep brachytherapy safe and make it even safer!

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THANK YOU FOR YOUR ATTENTION