Unofficial translation from Finnish.
Legally binding only in Finnish and Swedish.

REGULATION STUK S/11/2021

Radiation and Nuclear Safety Authority Regulation on the Use of Non-Ionizing Radiation in a Cosmetic or Other Comparable Procedure

Adopted in Helsinki on 24 March 2021

In accordance with a decision of the Radiation and Nuclear Safety Authority, the following provisions are issued by virtue of section 162, subsection 3 of the Radiation Act (859/2018):

Section 1
Scope of application

This regulation applies to a cosmetic or other comparable procedure as referred to in section 162 of the Radiation Act that is performed somewhere else than in a health care unit as referred to in the Act on the Status and Rights of Patients (785/1992).

Section 2
Determination of exposure

The undertaking shall determine with a reliable method the exposure to skin and other tissues arising from the procedure prior to the commissioning of the equipment.

Section 3
Observing contraindications

The undertaking shall, prior to the commissioning of the equipment, define the factors related to the state of health or other equivalent circumstance that prevent the safe execution of the procedure (contraindications).

The client shall be informed of the contraindications prior to the planned procedure.

Section 4
Procedures exposing to ultraviolet radiation

When the skin is exposed to artificial ultraviolet radiation in a sunbed, the exposure may exceed the public exposure limits if:

1) the client is provided with sufficient information to choose such irradiation duration that no immediate adverse effects arising from short-term exposure will occur;
2) the annual effective radiant exposure of ultraviolet radiation to the skin does not exceed 5 kJ/m^2;
3) the effective irradiance of the ultraviolet radiation to the skin does not exceed 0.30 W/m^2.

The timer of the sunbed shall be so adjusted that the effective dose of a single exposure does not exceed 100 J/m^2 with the shortest duration and does not exceed 600 J/m^2 with the longest duration.

The provisions on determining the effective radiant exposure and irradiance are set out in Annex 1.

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Section 5
Procedures exposing to optical radiation

Exposure to optical radiation may exceed the exposure limits when using an appliance that meets the requirements of the standard SFS-EN 60335-2-113.

Laser product may be used locally on the skin if:

1) the duration of the exposure is longer than 0.25 seconds;
2) the accessible emission of the laser equipment does not exceed 500 mW as determined with a 3,5 mm aperture placed at the closest point of access;
3) no pain relief is used;
4) the procedure is immediately stopped if it causes a sensation of pain.

Section 6
Procedures exposing to electromagnetic fields

The specific absorption rate (*SAR*) induced on the subject's body by an electromagnetic field may exceed the public exposure limits if the SAR does not exceed the value defined in the table.

Frequency range	Average whole-body SAR*) (W/kg)	Local SAR*) in the head and trunk (W/kg)	Local SAR*) in the limbs (W/kg)
100 kHz–6 GHz	0.4	10	20
*) The specific absorption rate (SAR) induced on the body by an electromagnetic field is determined as an average over six-minute periods. The local SAR is determined as an average over 10-g tissue mass.			

Section 7
Procedures exposing to ultrasound

When ultrasound is applied to the body through skin contact or medium that effectively transfers ultrasound energy to the body, the exposure may exceed the exposure limit in parts of the body other than the eyes if:

1) the ultrasound intensity averaged over the effective cross-sectional area of the beam and the duration of the exposure is not more than 3 W/cm^2 and the spatial peak value of the ultrasonic intensity averaged over the duration of the exposure is not more than 24 W/cm^2 or the thermal index of the ultrasound is smaller than 1.0 and the mechanical index smaller than 0.7;
2) the exposure is not directed at the same area for a longer period than is necessary; and
3) pregnancy has been included in the contraindications.

In procedures carried out near the eye, special care shall be taken to ensure that the intensity of the ultrasound in the eye does not exceed than 0.05 W/cm^2 or the thermal index of the ultrasound in the eye is not more than 0.7 and the mechanical index of the ultrasound in the eye is not more than 0.2.

Further provisions on determining the thermal and mechanical index are set out in the Decree of the Ministry of Social Affairs and Health on the limitation of public exposure to non-ionizing radiation (1045/2018).

Section 8
Entry into force and transitional provisions

This regulation enters into force on 1 April 2021 and is valid until further notice.

Provisions on the transitional period concerning the exposure limits for intense pulsed light equipment and ultrasound equipment are set out in the Decree of the Ministry of Social Affairs and Health on the limitation of public exposure to non-ionizing radiation. In a procedure where the exposure is greater than the limit value, this regulation shall be complied with irrespective of the transitional period, with the exception of section 7, subsection 1, paragraph 1 and subsection 2.

This regulation applies to any matters pending on the date of its entry into force.

This regulation repeals the Radiation and Nuclear Safety Authority Regulation on the Use of Non-Ionizing Radiation in a Cosmetic or Other Comparable Procedure (STUK S/5/2018).

In Helsinki 24 March 2021

Director General Petteri Tiippana

Director Tommi Toivonen

Availability of the regulation, guidance and advice

This regulation has been published as part of the regulations issued by the Radiation and Nuclear Safety Authority (STUK) and it is available from the Radiation and Nuclear Safety Authority.

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ANNEX 1

The effective irradiance E_{ery} of ultraviolet radiation shall be determined as follows:

$$E_{ery} = \int_{\lambda=250\ \mathrm{nm}}^{\lambda=400\ \mathrm{nm}} E_\lambda(\lambda) \cdot S_{ery}(\lambda) \cdot d\lambda,$$

and the effective dose H_{ery} of ultraviolet radiation shall be determined as follows:

$$H_{ery} = \int_0^t \int_{\lambda=250\ \mathrm{nm}}^{\lambda=400\ \mathrm{nm}} E_\lambda(\lambda, t) \cdot S_{ery}(\lambda) \cdot d\lambda \cdot dt.$$

The relative spectral sensitivity factor $S_{ery}(\lambda)$ shall be determined as follows:

$S_{ery}(\lambda)$ [dimensionless] 250 nm–400 nm

Wavelength [nm]	$S_{ery}(\lambda)$
$250 \leq \lambda \leq 298$	1
$298 < \lambda \leq 328$	$10^{0.094(298-\lambda)}$
$328 < \lambda \leq 400$	$10^{0.015(140-\lambda)}$

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