

Magazine section

Snapshots

Regulations

New German Law on Non-ionizing Radiation Protection

A new law concerning the protection of human subjects when treated with non-ionizing radiation came into effect in Germany in August 2009 (“Gesetz zum Schutz vor nichtionisierender Strahlung bei der Anwendung am Menschen”, NiSG). This law provides extensive regulatory measures and provisions necessary to protect humans against adverse effects resulting from the use of non-ionizing radiation.

It is not only applicable for equipment used for medical application of non-ionizing radiation in medicine and dentistry but also for non-medical commercial applications, in particular cosmetic use. This means that the NiSG also applies to manufacturers and users of intense pulsed light sources (IPL), laser devices for permanent hair removal, and devices for cavitation and microdermabrasion.

The law defines non-ionizing radiation as:

- electric, magnetic and electro-magnetic fields in a frequency range from 0 Hz to 300 GHz,
- optical radiation in the wavelength range of 100 nm to 1 mm, and
- ultrasound in the frequency range of 20 kHz to 1 GHz.

The law links the operation of the relevant devices to the fulfillment of special conditions. Devices that produce non-ionizing radiation may only be used for cosmetic purposes or other applications on humans which are not medical or dental, if they comply with requirements that have still to be determined by legal regulation.

Accordingly, the following requirements have to be part of the legal regulation:

- Defined radiation limit values that must not be exceeded (in contrast to medical applications, the limit values in cosmetics should not, under any circumstance, be exceeded. The benefit/risk assessment anchored in the NiSG §2, which allows specified thresholds to be exceeded by the physician, are only relevant in the medical field).
- The time intervals at which the devices must be checked.
- An obligation to provide advice and information prior to the device being operated.
- If necessary, a requirement for installation of warning signs.
- Requirements for the protection of minors.
- Requirements for specialist knowledge/training of the operator.
- Verification for the authorities.

With this, the use of non-ionizing radiation in cosmetic devices will be regulated in detail. However, exactly what form they will take by legal regulation remains to be seen.

One crucial aspect will most certainly be the ‘requirement for specialist knowledge of the operator’.

It could be specified that the operator must have an ‘alternative practitioner license’ in order to be able to operate the device.

Currently the monitoring authorities of various German federal states are of the opinion that different cosmetic treatments such as IPL and laser treatments should only be carried out by persons that have an alternative practitioner license, according to the Alternative Medical Practitioners Act (“Heilpraktikergesetz”, HPG).

However there will possibly be only very limited requirements such as the participation on a laser safety course. For more information about the law please visit

<http://www.gesetze-im-internet.de/nisg/index.html>
(13.03.2012).

Advanced training courses

Laser safety courses



DEUTSCHE GESELLSCHAFT
FÜR LASERMEDIZIN e.V.

Fundamental and very specific knowledge and skills are essential for the use of medical lasers. There are a number of laser courses that satisfy the training concept of the German Society for Laser Medicine (DGLM) e.V. The following listed courses follow the guidelines of the DGLM:

Berlin, LMTB & Ev. Elisabeth Hospital: Laser medicine from A to Z/Lasermedizin von A bis Z

Dates: 2–4 June 2012

22–24 September 2012

24–26 November 2012

Registration: Gabriele Beckmann, LMTB, Fabeckstr. 60-62, 14195 Berlin; Tel.: +49 (0)30 844923-24, Fax: +49 (0)30 844923-99

URL: http://www.lmtb.de/medizintechnik/kurse_m_de.php?id=4

Berlin, LMTB: Lasers in Dentistry/Laser in der Zahnmedizin

Date: 28–29 September 2012
Registration: Gabriele Beckmann, LMTB, Fabeckstr. 60-62, 14195 Berlin; Tel.: +49 (0)30 844923-24, Fax: +49 (0)30 844923-99
URL: http://www.lmtb.de/medizintechnik/kurse_z_de.php?id=4

Ulm, ILM: Laser safety course "Lasers in Medicine"/ Sachkundekurs "Laser in der Medizin"

Dates: 27 June 2012
17 October 2012
Registration: Gudrun Gruoner, ILM, Helmholtzstr. 12, 89081 Ulm; Tel.: +49 (0)731 1429-511, Fax: +49 (0)731 1429-422
URL: <http://www.ilm-ulm.de/fortbildung/kurse.html>

The training concept of the DGLM proposes a two stage training program. This usually comprises:

- a two-day basic course to convey general laser knowledge and the basics of medical application as well as a laser safety course, and
- a one-day either a specific subject area or a general clinical laser course.

The chronological order and the time frame of the course are recommended but by no means obligatory. Accreditation of the clinical courses by the DGLM requires recognition of the relevant state medical chambers. The point system is applicable.

The guidelines for further education for doctors apply if the training regulations of individual medical faculties require a corresponding qualification certificate.

After successful participation, the DGLM issues an overall certificate for all specialist fields. Necessary requirements for the issue of the certificate is the proof of qualification as a laser safety officer, and the proof of at least 12 points for clinical laser courses or corresponding internships at recognized laser centers.

It is planned to standardize the training and accreditation within the framework of the European Laser Association (ELA).

For further information please visit

<http://www.dglm.org>
(14.03.2012).

Additional Qualifications: Postgraduate and Professional Development Course in Aesthetic Laser Medicine

The University of Greifswald is the first university in Europe to offer a post graduate course in Aesthetic Laser Medicine.

Students who successfully complete the international course are awarded the Diploma in Aesthetic Laser Medicine (DALM). A good introduction to the study program is provided by:

Hammes S. Qualitätssicherung in der Ästhetischen Medizin durch universitäre Weiterbildung. Berlin, Heidelberg: Springer-Verlag; 2012.

- **Entry requirements:** A first degree from a German university or an overseas qualification of an equivalent standard. Professional experience may be accepted in certain cases.
- **Duration:** max. 2 years
- **Central Student Advisory Service:** Rubenowstr. 2, 17487 Greifswald, Germany; Tel.: +49 (0)3834 86-1293, Fax: +49 (0)3834 86-1282, e-mail: zsb@uni-greifswald.de

For further information please visit

<http://www.uni-greifswald.de/en/study/postgraduate-and-professional-development-courses.html>
(14.03.2012).

News from the laser societies**2012 Ellet H. Drake Memorial Award**

Brian Biesman, MD, assistant clinical professor of Ophthalmology and Visual Sciences at Vanderbilt, has been named to receive the 2012 Ellet H. Drake Memorial Award from the American Society for Laser Medicine and Surgery (ASLMS).

The award recognizes Biesman's contributions in the use of lasers for patient care, in laser research and in teaching other physicians best practices in laser medicine.

"I'm particularly proud to receive recognition from my colleagues in the field of laser medicine," said Biesman, also director of the Nashville Center for Laser and Facial Surgery. "During my career it has been extremely gratifying to have played a part in developing medical applications for laser technology that can potentially benefit millions of patients worldwide."

Biesman specializes in laser and facial surgery with a focus on eyelid plastic and reconstructive surgery and technology-based rejuvenation procedures.

His current research interests include technology-based cutaneous rejuvenation, novel approaches to noninvasive tissue tightening, transcutaneous and minimally invasive lipolysis, soft tissue volume augmentation for facial rejuvenation, transcutaneous delivery of botulinum toxin, technology-based modification of facial muscles, laser-enhanced drug delivery, home-use lasers and light devices, advances in ablative fractional skin resurfacing, cutaneous repigmentation and low-level light therapy for photorejuvenation.

The 4300-member American Society for Laser Medicine and Surgery Inc. is the world's largest professional organization dedicated to promoting excellence in patient care by

advancing laser applications and related technologies (source: Vanderbilt University Medical Center's Weekly Newspaper).

See also: <http://www.aslms.org> (16.04.2012).

Books

Mukherjee S. Der König aller Krankheiten: Krebs – Eine Biografie. Köln: DuMont Buchverlag; 2012



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Siddhartha Mukherjee MD, DPhil, won the 2011 Pulitzer Prize for general nonfiction for his book “The Emperor of All Maladies: A Biography of Cancer.” Mukherjee has received worldwide acclaim by cancer researchers and book critics alike. His book details how diagnosis and treatment of human cancers evolved from ancient Egypt to current times. The

book will take the reader through the history of cancer and where we stand today with cancer treatments and research.

Mukherjee is an assistant professor of medicine at Columbia University. He received his bachelor's in biology from Stanford University, earned a doctorate from the University of Oxford as a Rhodes Scholar, and received his medical degree from Harvard Medical School (source: Johns Hopkins Medicine).

A strong recommendation of the book comes also from Dr. Lilge, one of the editors-in-chief of *Photonics & Lasers in Medicine*: “While today individualized cancer detection, diagnosis, therapy and support is often written into the mission statements of the large cancer societies and research institutes, the book provides a fascinating inside into the various major hypothesis (as recent as the 1970s) which aimed at identifying overarching principles in the generation and propagation of cancer. None of these false approaches are discussed in today's oncological research and hence the path oncological research has taken was at risk of being lost. Siddhartha Mukherjee brings the history of cancer research and our understanding of cancer back into our mind. The book is easy to follow and provides tantalizing inside even to somebody working for over 15 years in a cancer research institute. The one little drawback of the discussion in the book is that the physical approaches of treatment of cancer are disproportionately less described than the pharmaceutical approaches. So do not expect to read about all the details of laser therapies tested for cancer therapy, not for detection.”

The 2012 Pulitzer Prize winners and nominated finalists will be announced on April 16, 2012.

More information about this you can find at

<http://www.pulitzer.org/biography/2011-General-Nonfiction> (14.03.2012).