By Paul McGinn

New EU law will create significant impact on ophthalmic lasers

The European Union is on the verge of introducing a major new law to regulate the use of ophthalmic lasers.

The new Optical Radiation Directive, which is currently in the latest stages of approval by the EU, will introduce new safeguards for anyone who works around a laser or other source of artificial light.

Under the directive, anyone who operates a laser – including any ophthalmologist, clinic, or hospital – must introduce a number of health and safety checks to reduce the risk that the laser could burn or blind any staff member who works near the laser.

In particular, the directive places a specific requirement on an ophthalmologist who owns lasers and who also employs anyone to help operate those lasers to undertake risk assessments about each of those lasers, regardless of the type or use of that laser.

"The employer, in the case of workers exposed to artificial sources of optical radiation, shall assess and, if necessary, measure or calculate the levels of exposure to optical radiation to which workers are likely to be exposed so that the measures needed to restrict exposure to the applicable limits can be identified and put into effect," the Directive reads.

The directive provides that after carrying out such a risk assessment, an ophthalmologist or other laser operator must minimise any risk uncovered by the assessment, including any risk involving a level of radiation that the operator cannot reduce below the recommended level.

Mandatory action plan

In such cases, the directive states that the laser operator shall "devise and implement an action plan" based on technical and organisational changes. The plan should address:

- Selecting working methods that reduce the risk from optical radiation;
- Choosing equipment that emits less optical radiation, taking account of the work to be done;
- Adopting technical measures to reduce the emission of optical radiation, including the use of interlocks, shields, and other health protection mechanisms;
- Using appropriate maintenance programmes for work equipment,
- Changing workplaces and workstation systems;
- Altering the design and layout of workplaces and workstations;
- Limiting the duration and level of the exposure;
- Finding more appropriate personal protective equipment;
- Consulting and advising the manufacturer of the laser equipment.

In addition to minimising the risks posed by the laser, ophthalmologists and other laser owner-operators must also ensure that workers receive any necessary information and training to help them minimise those risks.

That information must include:

- Exposure limit values and the associated potential risks;
- Results of any assessment, measurement or calculation of the levels of exposure to optical radiation; with an explanation of the significance and potential risks from such exposure;
- How to detect adverse health effects of laser exposure and how to report them;
- Circumstances in which workers are entitled to health surveillance;
- Descriptions of safe working practices to minimise risks from exposure;
- Explanation of the proper use of appropriate personal protective equipment.

If the risk assessment identifies any "significant" risks to staff members from the laser, the ophthalmologist must establish a health surveillance programme to monitor the potential effects of lasers on the employees.

According to the directive, each EU country must introduce a health surveillance programme and give the appropriate national authority the legal power to monitor and enforce the programme.

Optical Radiation Directive 15 years in the making

Although scientists have known the health and safety risks from lasers since their invention, the European Union has taken almost 15 years to introduce its own health and safety laws for their use.

On 8 February 1993, the EU's initiator of laws, the European Commission, proposed a directive to establish minimum health and safety requirements regarding the exposure of workers to the risks arising from "physical agents."

In 1994, the EU narrowed the proposed law to establish minimum requirements for four types of physical agents – noise, mechanical vibration, electromagnetic fields, and optical radiation.

By 1999, EU officials decided, based on the very different characteristics of the four physical agents, to introduce separate directives for each of the physical agents. Since then, the EU has adopted directives on vibration, noise, and electromagnetic fields.

The European Council – which includes representatives from each EU government – adopted their version of the optical radiation directive on April 18.

Since that time, the Commission and European Parliament have discussed amendments to that proposal.

One of the biggest changes has been to remove from the directive a proposal to create European standards for exposure to natural sources of radiation like sunlight. The EU had proposed the inclusion of sunlight to reduce the number of people who die from melanoma each year. Some 15,000 persons in the EU die from melanoma each year.

The construction industry, in particular, opposed such standards, arguing that construction workers who work outdoors expose themselves to no more radiation from sunlight than do members of the public when they are outside. The construction industry also argued that the levels of radiation from sunlight depend on geography; as a result, Europe-wide exposure levels would most probably penalise construction firms in southern Europe. In addition, the construction industry said that the EU had already recognised individual EU countries as the appropriate regulators for exposure levels to such carcinogens as radon, which is responsible for 20,000 lung cancer deaths a year in the EU.

"Given that the form of the radiation that a worker would be exposed to is, in principle, identical to the radiation a member of the public would be exposed to, it seems heavy-handed to make the legislative leap from zero legislation to directive, when a recommendation has been used to improve health and safety in analogous circumstances," the UK-based Federation of Master Builders has argued.

Worker health and safety behind new directive

The proposed Optical Radiation Directive, which aims to reduce the health risks posed by lasers and other artificial sources of light, owes its legal foundation to the European Union's commitment to protect workers.

The European Treaty – which is the constitution of the EU – gives the EU the power to introduce laws to improve "the working environment to protect workers' health and safety."

Given such an all-encompassing commitment to the safety and health of workers, the proposed directive makes no distinction between the long-term effects and short-term effects of optical radiation.

To reduce those effects to a minimum, the directive introduces exposure limit values for all sources of artificial light, including lasers. The values are essentially based on the recommendations established by the International Commission on Non-Ionising Radiation Protection and the International Electrotechnical Commission.

These scientifically based guidelines, which are conservatively based, are designed to prevent the acute and long-term effects to the eyes and the skin that can occur at extremely high levels of exposure. The exposure limit values prescribed correspond to those developed by other independent scientific advisory bodies that work in this area, notably the American Conference of Governmental Industrial Hygienists, the UK's National Radiological Protection Board, and the Health Council of the Netherlands.

Business leaders worry that directive will increase costs and bureaucracy

Europe's business owners have warned ophthalmologists and other owners of laser-based machines that the proposed Optical Radiation Directive could cost them dearly in money, time, and paperwork.

"This plan will not improve workers' health and safety, but will just add to the bureaucracy faced by businesses operating in the EU," says Paul Kelly, director of the Irish Engineering Enterprises Federation. "No proper impact assessment was carried out on the proposal and it is written in language which is so complex that it is completely beyond the understanding of most employers unless they were to be given detailed guidance."

Business owners have railed against the breadth of the directive because it would require them to carry out checks on all sources of optical radiation in the workplace, including computer scanners, photocopiers, and even CD and DVD players.

In a bid to reduce any anxiety caused by the new directive, the European Parliament has called on the EU to publish a practical guide on the directive to help employers, in particular managers of small and medium-sized enterprises to understand the directive's technical provisions.

Directive could improve chances of successful lawsuit

In imposing a legal duty on laser operators to introduce new safeguards for their employees, the proposed Optical Radiation Directive will make it easier for employees to sue their employing ophthalmologist if they injures themselves in a laser accident.

As soon as an EU country adopts the directive, the courts in that country will apply the terms of the directive to any lawsuit by an employee injured by a misdirected laser beam.

Under the directive, all employers who operate a laser – including any ophthalmologist or clinic – must conduct a risk assessment of the laser and undertake any necessary steps to reduce the risk that the laser will injure an employee.

If a court finds that the ophthalmologist failed to conduct a risk assessment or undertake appropriate safety measures to reduce the risk of injury, the court could hold the ophthalmologist responsible for the injury and order the ophthalmologist to compensate the employee.

At present, an employee injured by a laser can only succeed if he or she can prove that the ophthalmologist failed to follow a national medical laser law – if it exists – or if the ophthalmologist failed to follow the appropriate industry or professional standard or guideline for using the particular laser.

Under the directive, the health surveillance programme will require ophthalmologists and other laser owner-operators to create health records for their employees and create rule about how ophthalmologists and other laser owner-operators should update such records.

Health surveillance

The directive specifies that the health records should include a summary of the results of any health surveillance carried out.

The directive also will require ophthalmologists to supply copies of the appropriate health records to the appropriate competent authority in their own country and to ensure that they treat such records with confidentiality. Also, the directive directs that individual workers will have access to their own personal health records.

If the health surveillance discovers that a worker suffered an accident or developed an identifiable disease or adverse health effect because of exposure to optical radiation at work, the directive specifies a step-by-step follow-up:

- The worker shall be informed by the doctor or other suitably qualified person of the result which relates to him personally. The worker shall, in particular, receive information and advice regarding any health surveillance which he should undergo following the end of exposure;
- The employer shall be informed of any significant findings of the health surveillance, taking into account any medical confidentiality;

The employer shall:

- review the risk assessment already carried out;
- review the measures provided for to eliminate or reduce risks identified by the assessment;
- take into account the advice of the occupational healthcare professional or other suitably qualified person or the competent authority in implementing any measure required to eliminate or reduce risk, including the possibility of assigning the worker to alternative work which carries no risk of exposure exceeding the appropriate exposure limit value;
- arrange continued health surveillance and provide for a review of the health status of any other worker who has been similarly exposed. In such cases, the competent doctor or occupational health care professional or the competent authority may propose that the exposed persons undergo a medical examination.

Risk assessment and management

Assessing the risk posed by any ophthalmic laser – and correcting the deficits discovered by such an assessment – represent the main duties for ophthalmologists who own and operate lasers, under the proposed Optical Radiation Directive.

In assessing the risk of their lasers, ophthalmologists must "give particular attention" to a number of issues, according to the directive. Those issues include:

- Maximum level, wavelength range, and duration of exposure by workers to lasers and other artificial sources of optical radiation;
- Exposure limit for any effects concerning the health and safety of workers who may be particularly sensitive to lasers;
- Possible effects on workers' health and safety resulting from workplace interactions between optical radiation and any photosensitising chemical substances;
- Indirect effects of lasers, such as temporary blinding, explosion or fire;
- Existence of replacement equipment designed to reduce the levels of exposure to optical radiation;
- Appropriate information obtained from health surveillance, including published information, as far as possible;
- Multiple sources of exposure to optical radiation;
- Classification of the laser concerned, based on the risk of it causing damage;
- Information provided by the laser manufacturers and associated work equipment in accordance with the any existing EU law.

Directive proposes strict penalties for violations

Although the directive does not state specific fines or jail sentences for those who fail to follow the directive, it does specify that EU countries must enact appropriate penalties for ophthalmologists or any other owners and operators of lasers who fail to follow the directive.

"These penalties must be effective, proportionate, and dissuasive," the directive states.

For the latest details of the proposed Optical Radiation Directive and other European Union initiatives, visit: http://www.eupolitix.com/EN/

Misdirected and reflected laser beams pose real risks to staff

Although ophthalmologists may be well versed in the risks of aiming a laser into the eye of a patient, they may overlook the real – albeit limited – risk that misdirected and reflected laser beams pose to their staff.

According to a leading laser scientist, nurses and technicians who work around lasers -- the focus of the new EU Optical Radiation Directive – are susceptible to many laser hazards.

"Nurses, surgical assistants, and other assisting staff are potentially exposed to misdirected laser beams," Dr Slaney writes in the "Ophthalmic Laser Safety" chapter of the textbook Lasers in Ophthalmology.

In particular, the use of lasers can pose a risk to staff members in situations where the laser beam reflects off of the cornea, a contact lens, or surgical instrument, Dr Slaney adds.

Assistants are potentially exposed to secondary reflections from contact lenses (and in some special procedures, from reflections from surgical instruments), whereas the surgeon's eyes are protected by filtration in the viewing optics," he writes. Secondary reflections can pose a hazard to anyone standing within one to two metres of the reflection, he adds.

Dr Slaney adds that ophthalmologists should remember that a family member or friend who may accompany the patient into the surgery area is also at risk of a misdirected laser beam and should also wear appropriate goggles.

Dr Slaney also notes that a potential cause for the accidental firing of a laser beam is the positioning of two foot switches too close together. One way to reduce such mistakes is to follow safety guidelines that recommend that each laser foot switch be covered and clearly labeled.

At least nine hazards posed by ophthalmic lasers

Lasers used by ophthalmologists can damage the eye or skin in at least nine ways, Dr Slaney notes.

In the "Ophthalmic Laser Safety" chapter of the Lasers in Ophthalmology textbook, he listed nine separate conditions that could arise from either a single or long-term exposure to a misdirected laser or other source of intense radiation:

- ultraviolet photokeratoconjunctivitis, or so-called "welder's flash";
- ultraviolet cataract;
- ultraviolet erythema;
- skin cancer;
- retinal burn;
- blue-light photochemical injury to the retina;
- near-infrared thermal hazards to the lens, including cataracts;
- thermal injury to the cornea and conjunctiva;
- skin burns.

Of course, most of the risks posed to the eye from brief misdirection of the laser can be adequately reduced with the use of appropriate eye protector, Dr Slaney states.