Cautious Optimism for Proposed European MRI Exposure Limit Exemption

By Marie Gethins

In 2004 Member of the European Parliament (MEP) Liz Lynne was Shadow Rapporteur on a proposed European Union directive for what is now the Alliance of Liberals and Democrats in Europe. EU Directive 2004/40/EC aimed to regulate worker exposure to electromagnetic fields. “I did a lot of research work on it,” MEP Lynne said. “I contacted medical experts and consulted manufacturers to understand what the limits would mean if applied.” For part of her background research, she attended a meeting held by physicians at a prominent Belgian hospital where radiologists expressed their concern that the directive could cause health care turmoil. “They were very worried that if the directive was applied, they would not be able to use magnetic resonance imaging [MRI] for research or in the clinic,” she said. However, she found political resistance when she highlighted these concerns. “People were not listening to the medical experts,” Lynne said. “Under the original legislation, MRI scanners would have been effectively banned from 2012.”

Although the directive passed, MEP Lynne continued to highlight the havoc it would produce for health care systems if implemented as scheduled in April 2008. Strong support came from other quarters when, in March 2007, the Alliance for MRI was formed. A coalition of 27 MEPs, 15 European and national-level patient groups, 13 scientific representative groups, and 28 institutional members of the European Society of Radiology, the Alliance for MRI also lobbied against implementing the directive. In October 2007, the European Commission proposed postponing the implementation deadline from April 2008 until April 2012 to allow time for analysis of what ramifications the directive could have in medical settings.

The commission launched a study in four European countries (Germany, France, Belgium, and the UK) to evaluate the directive’s implications on medical MRI use. The study results indicated that the directive would negatively affect scanning of vulnerable patients that required technician assistance and interventional MRI, such as used for brain tumor surgery. The directive could also hinder adoption of MRI device development or how newer scanners could be used in clinical trial research. Emma Greenwood, policy manager at Cancer Research UK, said, “Going forward, there was some concern that in research it would be possible to technically breach the limits as they are set out—for example, if you were moving the patient around during the scan.”

Yet in 2007, the European Commission invested approximately €6,000,000 in MRI development projects as part of the 7th Framework Programme for Research.

Not a Question of Worker Safety

Interest groups highlight that existing European safety legislation protects medical workers using MRI. MRI safety standard IEC/EN 60601-2-23 sets out criteria to minimize physiological effects to protect MRI operators, researchers, and patients. MEP Lynne said, “The Medical Device Directive covers MRI scanners already.” UK research funders, including Cancer Research UK, also carefully considered worker safety. Greenwood said, “This directive added to quite extensive existing regulations and safety guidance on electromagnetic resonance exposure. We weren’t concerned that it would lead to a situation where workers weren’t being protected.”

András Palkó, M.D., president of the European Radiology Society and head of the radiology department at the University of Szeged, Hungary, believes Directive 2004/40/EC also did not take into account the extensive technical knowledge of radiologists and physicians compared with that of workers in other settings exposed to electromagnetic fields. “We clearly understand every second of operational exposure,” he said. “There are strict guidelines on how to operate MRI scanners and avoid risk.” Palkó noted that in almost three decades of medical MRI use, up to 500 million patients were scanned by MRI with magnetic fields set at amplitudes 100 times higher than the directive’s limits; virtually no evidence exists of harm to workers exposed to electromagnetic fields. “In a report by the UK Medicines and Healthcare Products Regulatory Agency, there were four adverse events in 100,000 scans,” Palkó said, “and all were the fault of the operators not following guidelines.”

Considering transitory peripheral nerve stimulation incidence, the report cites just one occurrence in 3 million scans. Palkó noted that MRI should be considered within the range of imaging options: “It has to be understood that computed tomography [CT] may produce ionizing radiation that can be as much as 10-fold higher than X-ray.”

New Metrics Needed

Hannah Heinrich, Ph.D., the scientific coordinator for the Safety in ElectroMagnetic Fields International Research Association and lead author of a paper reviewing the directive, reports, “Missing guidance; incomplete, outdated, and sometimes erroneous information;
and a lack of experience on the user side added to the confusion on how to deal with Directive 2004/40/EC.” Heinrich believes that fundamental flaws remain and calls for new measurement metrics. “The need for complex, time-consuming, and therefore expensive numerical calculations in order to show if the exposure situation at a workplace is compliant with the exposure limit values, as soon as the action values are exceeded, created a huge burden especially for small- and medium-sized enterprises,” she said.

MRI an Essential Tool
Palkó stressed that MRI is an essential diagnostic tool for diseases of the central nervous system; bone, liver, and pelvic disorders; and pancreatic and neurological tumors. MRI can be far more effective than CT at detecting small tumors, particularly in dense tissue. Equally important is MRI’s role in guiding interventional surgery. “CT-guided surgery is not an option, as it is not very accurate,” Palkó said. “We are speaking about patients’ lives; without MRI, some patients would die.” MEP Lynne concurs: “This legislation would lead to illness and death of patients.”

MRI’s role in European health care research is also vital. A recent UK breast cancer survival study (Radiology 2011;260:68-78) would not have been possible without the directive implementation delay. Researchers used contrast-enhanced MRI to measure vascularity. The kinetic MRI parameter inflow transfer constant calculates the transfer of contrast between the blood plasma and the tumor. “When you are
looking at potential implications of the directive, it’s almost the not knowing how the field is going to develop, where research is going to take you, and how MRI could be used for clinical care,” Greenwood said. “You don’t want to put something in place that is going to damage the potential in that area.”

Geographic Variation
According to 2011 Organization for Economic Co-operation and Development data and the 2010 *Le Quotidien du Médecin* survey by Imagerie Santé Avenir, many European countries still lag behind MRI installations in the U.S. and Japan. Despite recessionary budget tightening, most European health care system plans include additional MRI purchases. Palkó said, “EU member states have invested a lot in not just MRI equipment, but also research and training. It’s a huge amount of investment.”

On average, European countries have installed 17 MRI scanners per 1 million people. However, the level of installations varies widely across Europe. France has 8.7 MRI scanners per 1 million people; Germany, 20; and the UK, 5.9. By comparison, U.S. and Japanese installations have 25.9 and 43.1 per 1 million people, respectively.

Palkó said that international colleagues are “completely surprised” by the directive’s electromagnetic field limits. “There is no other region in the world where this is happening. American colleagues don’t understand it, and when we explain it they are very surprised,” he said.

Directive Already Law in Several Member States
Progress on amending the directive has been sluggish since the delay was announced. “The European Parliament and Council decision on evaluating a proposed amendment to the directive text has been slower than we hoped,” Palkó said. With implementation scheduled for April 2012, pressure increased this year for a clear decision on medical MRI worker exposure limits in the directive.

On June 14, 2011, the European Commission adopted a proposal to revise the directive, including a derogation for medical and research MRI use from the worker exposure limit values. The Alliance for MRI and other interest groups welcomed the move, but experts remain cautious in their optimism. “We hope the outcome will be positive,” Palkó said. Cancer Research UK’s Greenwood expressed concerns. “We know that some of the other member states are necessarily as supportive in their position as the UK is to exempt MRI because of the length of time it has taken to draft the amendment,” she said. “Some of them have already started to implement, so if there is a revision they will have to go back.” Several member states—including Latvia, Lithuania, Estonia, the Czech Republic, the Slovak Republic, Austria, and Italy—have incorporated the directive into national law. However, in 2008, the Italian Parliament voted to postpone implementation of the legislation, while many hospitals in the other member states are ignoring its implications. The Czech, Slovak, Austrian, and Italian radiological societies are members of the Alliance for MRI.

MEP Lynne expected a report will be available by yearend, followed by a vote in the European Parliament next year. Although more optimistic than a few months ago, Lynne believes that hurdles remain in raising political awareness of the directive’s potential ramifications for European health care. “It’s still all to play for,” she said.