Written evidence submitted by the Institute of Physics and Engineering in Medicine (IPEM) to the House of Commons Public Bill Committee in relation to the Retained EU Law (Revocation and Reform) Bill 2022-23

About IPEM

- IPEM is a professional association and Learned Society with around 4,700 members working in hospitals, academia and industry, who are medical physicists, clinical and biomedical engineers and technologists working with applications of physics and engineering applied to medicine.
- Our mission is to constantly improve human health by the application of physics and engineering to the prevention, diagnosis and treatment of disease through research, innovation, education and clinical practice.
- As a charity, IPEM's aim is to promote for the public benefit the advancement of physics and engineering applied to medicine and to advance public education in the field. We do so by supporting and publishing research and supporting the dissemination of knowledge and innovation through project funding and scientific meetings; and by setting standards for education, training and continuing professional development for healthcare scientists and clinical engineers.
- In compiling this response, IPEM consulted with members of its Clinical and Scientific Computing Special Interest Group (SIG), Diagnostic Radiology SIG, Nuclear Medicine SIG, Radiation Protection SIG, Ultrasound and Non-ionising Radiation SIG, and the Science, Technology, Engineering, Research and Innovation Council (STERIC).

IPEM's response

1. One of the main issues with the proposed Bill is it introduces a great uncertainty in the regulatory framework of the UK with a significant risk of sweeping changes without adequate time to assess them.

2. The number of laws identified is significant and there are finite government resources to review them before the sunset deadline (including the possible extended sunset date). There is a risk of important regulations being sunset or poorly amended and equally the opportunity to make improvements missed purely due to the deadlines imposed.

3. The constitutional concerns raised, which have prompted this Bill, may exist within REUL, but the regulations identified by IPEM represent the framework for ensuring patient, public, and employee safety in the UK.

4. The UK, under the current regulations, follows and contributes to international best practice, with IPEM professionals contributing to international projects. Revoking such items would risk undermining the influence the UK has on the international stage.

5. The **briefing paper** on the Bill, published by Graeme Cowie on 17 October and held in the House of Commons Library, consolidates many concerns in Section 11, although the impact on health and safety is not explicitly identified. A few relevant sections from the paper are:
   - "The general nature of the Bill's provisions, combined with the sunset clauses, leaves the substantive fate of key policy areas unresolved."
   - "Sir Jonathan Jones KC put it in a webinar for the Hansard Society: The Explanatory Notes… give no indications of any particular legal or policy areas

which the Government thinks should either be retained or changed. So at the time of passing this Bill… neither Parliament nor businesses nor anyone else can know what the substantive law will be by the end of 2023[…]The default position… is that if no conscious decision is made to keep a particular piece of retained EU law, with or without amendments, or if indeed a piece of retained EU law is missed by accident, it will automatically expire on the sunset date with no further involvement by Parliament at all. At the moment we simply don't know what will happen to any particular law"

- "George Peretz KC has said: A result of the sunset clause is that Government departments might be tempted to turn up to Parliament in November to December 2023 with whole rafts of replacement revocation legislation… Parliament would otherwise have been in a position of being able to prevent that because changes [would sometimes] require a positive vote in both Houses of Parliament to get it through. But when Parliament has essentially got a gun to its head, it's faced with a whole pile of legislation about which there may be pretty substantial objections. But the message is unless you get it through, I'm afraid the rules will simply fall away. That makes Parliament's position extremely difficult. Now perhaps one would be unduly cynical to suggest that that was being planned, but it's certainly a possibility if by accident if not intention that that would happen."

6. Given this review involves more than 2,400 individual pieces of legislation, there is clearly a potential for gaps to be left in relation to crucial ionising radiation legislation. This has serious implications in terms of both staff and patient safety and wider implications outside of the health service including industry and other areas.

7. While we recognise that given our departure from the EU, UK law should now take precedence over EU-derived law, it seems unnecessary to have a hard deadline for process of review and revocation, which carries a risk of leaving gaps in legislation if the process is incomplete at the end of 2023.

8. At the extreme, the de-regulation of activities involving ionising radiation is possibly very dangerous. As an example, the Ionising Radiation Regulations 2017 (IRR) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER) transposed EU Directives into UK legislation. They are not "copy and pasted" but *adapted* to the UK while still meeting the aims of the directive. These laws therefore remain relevant to the UK as a sovereign state outside of the EU, no matter of their original basis.

9. Many departments have only recently fully implemented the changes in IRR and IRMER 2017, with some professional guidance lagging behind by a few years. The regulators are also undergoing changes because of the International Atomic Energy Agency's inspection of UK radiation regulators at the end of 2019.

10. The Medical Device Directive, if this is repealed without a successor in place, runs the risk that anyone can make electronic devices or software without being in breach of regulations. While most established manufacturers will continue to comply with MDD or EU MDR (for export to EU), there may well be some who will – intentionally or not – create and sell unsafe medical devices.

11. The removal of the Control of Artificial Optical Radiation at Work Regulations 2010 (S.I. 2010/1140) would be detrimental to the safe operation of artificial optical sources, and in particular non laser ones in academic and healthcare settings. Besides the generic Health and Safety at Work Act 1974, this is the only specific piece of regulation which ensures staff are provided with adequate controls and protective measures. It is often cited to ensure phototherapy centre staff are given

basic PPE and controls. In addition, the UK implementation was developed in collaboration with UK experts in the field from the Health Security Agency (previously HPA and PHE).

ENDS