Written evidence submitted by the Institute of Physics and Engineering in Medicine (IPEM) to the House of Commons Science and Technology Committee inquiry on Brexit, Science and Innovation: Preparations for 'No-Deal' - January 2019

About IPEM

- IPEM is a professional association and Learned Society with 5,200 members working in hospitals, academia and industry, who are physicists, engineers and technologists working with applications of physics and engineering applied to medicine and biology.
- As a charity, IPEM's aim is to advance the application of physics and engineering to medicine for the public benefit and to advance public education in this field.
- The following response was collated from members of IPEM's Special Interest Groups, who were asked for their views on the effect of a "hard Brexit" on their ability to perform the work of their departments (within the National Health Service, the research sector and industry).

Executive summary

- There are real concerns that as the UK will be 100% dependent on deliveries from Europe, around 850,000 patients who undergo a nuclear medicine test using a radioisotope called technetium-99m, could be affected by a "hard Brexit".
- Unless the Medicines and Healthcare products Regulatory Agency develops an exemption, all radiopharmaceuticals entering the UK will be required to be batch tested for purity, adding to delays and reducing their usefulness.
- Due to expected congestion at Calais, the prime route for the importation of radioisotopes would be by air. This will depend on there being uninterrupted air travel into and out of the UK. Northern Ireland could be particularly badly affected by a "hard Brexit" and nuclear medicine physicists do not think they could continue to offer a full nuclear medicine service.
- No documentary evidence has been seen to give support to reassurances that medical radioisotopes arriving in the UK will have expedited customs clearance.
- The relevant regulations governing the transport of radioactive materials are not yet available and if a fully operational regulatory system is not available in sufficient time to allow operators to be compliant at the time of the UK's departure from the EU, this could further delay delivery of radioisotopes.
- Many medical devices require the use of calibration and installation kits held at stores on mainland Europe. Some devices are also repaired or calibrated abroad. The transport uncertainties and potential customs issues will mean an increased risk of downtime.
- A 2017 workforce survey found 17.8% of the medical physics and clinical engineering workforce originated from overseas, with 9.7% being from the European Economic Area. This illustrates the extent to which the UK is dependent on recruiting from abroad.
- The UK's prime position in medical research is threatened by withdrawal from the EU and this would be made much worse by a "hard Brexit".
- As part of the European Medicines Agency (EMA) the UK is seen as part of a larger market. If we are outside the EMA and do not have full reciprocity between the

MHRA in the UK and the EMA (likely to happen in a "hard Brexit"), the UK will be seen as a new, small market. This will require the UK to develop its own separate authorization process and as a small market will become a less attractive as a place to introduce new products and services.

- If there is a "hard Brexit" WTO tariffs will apply, which may be as high as 10-30% on any imported goods. It would be hoped the government would reduce tariffs on medical equipment, radiopharmaceuticals and radionuclides to be zero rated.

IPEM's response

Supply of radioactive material:

1. There are about one million diagnostic nuclear medicine tests performed in the UK every year. About 150,000 of these use PET technology, and nearly all of these use a radiopharmaceutical called F-18 fluorodeoxy glucose (FDG). The radioisotope used, F-18, has only a 2 hour half-life so is normally made within 60 miles of the hospital where it is used. At the moment we do not feel this will be affected by a "hard Brexit", except for Northern Ireland. The remaining 850,000 UK patients have a different type of nuclear medicine test and this uses a radioisotope called technetium-99m, with a 6 hour half-life. At present the technetium-99m comes from the radioactive decay of a molybdenum-99 generator. The half-life of the molybdenum-99 is 66 hours, so a single generator can normally provide enough technetium-99 for a week's work. Any missed or delayed delivery will seriously impact on the number of technetium-99m labelled radiopharmaceuticals that can be prepared for any given day. These generators are made from molybdenum, which at present is primarily sourced from Europe, Australia and sometimes South Africa. The factories making these generators are in the UK (at the Grove Centre), Belgium and the Netherlands. We were informed in a letter in June 2018 that the only UK production of these molybdenum generators at the Grove Centre near Amersham in Buckinghamshire will cease by the end of Q1 2019, with production transferred to Belgium. This could coincide with the date of a "hard Brexit". This would mean that, whatever happens, the UK would become 100% dependent on deliveries from Europe for those generators delivered after 30 March 2019. (Source the British Nuclear Medicine Society)
2. The isotope Iridium-192 has a half-life of approximately 74 days and is used for the vast majority of high dose rate brachytherapy cancer treatments, in particular gynaecological cancers. This isotope is again sourced from the EU and, whilst the longer half-life could provide a larger window of flexibility to interruptions in supply than some of the isotopes already discussed, nevertheless, the consequences on patient treatment could be significant if the supply were to be disrupted as sources are routinely changed every three to four months. There could also be disruption to the supply of Radium-223, which is used for metastatic prostate cancer, and which has a half-life of approximately 11 days, as it is manufactured in Norway but has to pass through Germany where the clinical radiopharmaceutical is manufactured.
3. Similar concerns are also present for radionuclide therapies, most commonly Iodine for thyroid cancer and hyper-activity and Radium for prostate cancer. These products are either completely or partly manufactured within the EU; any disruption in supply will compromise patient outcomes.

Pharmaceutical batch testing:

4. Once the UK leaves the EU in a "hard Brexit" it will legally become a "third country" when considering any drug import or export. Unless the Medicines and Healthcare products Regulatory Agency (MHRA) develops an exemption, it will be required that all radiopharmaceuticals entering the UK be batch tested for purity, adding to the delay and reducing usefulness.

Radionuclide transport issues:

5. At present a mixture of methods are used to bring molybdenum generators and other radioisotopes into the UK but for most of England the primary method is by road through the Channel Tunnel. Serge Goosemans, CEO and President of the European Isotopes Transport Association, clearly stated at a recent meeting in Poland that transfer by road would be difficult and of a higher risk if there is a "hard Brexit". Due to the expected congestion at Calais, the prime route for importation of radioisotopes would be by air. This will depend on there being uninterrupted air travel into and out of the UK. Also a substantial quantity of radioisotopes used in the UK originate in the Netherlands but KLM, which controls air cargo from Schiphol Airport, will not allow the export of radioisotopes from there. At present air transported radioisotopes for the UK are driven to Brussels, however, as Brussels Airport has a single north-south runway there can be significant delays from the prevalent westerly cross winds. Presently hospitals in Northern Ireland obtain radiopharmaceuticals by air via East Midlands Airport. Even now there are often delays so they are unable to use the radiopharmaceuticals when they do arrive due to the reduced activity arising from its radioactive decay during the delay. This has already led to significant problems providing a service. If there were to be any further delays because of customs checks from a "hard Brexit", colleagues from Northern Ireland do not feel they could continue to offer a full nuclear medicine service beyond Brexit, given the current arrangements and infrastructure. Similar issues are present for other diagnostic isotopes and for those used in therapy with varying degrees of patient impact.

Customs concerns:

6. Whilst there have been assurances that any medical radioisotopes arriving in the UK will have expedited custom clearance we have not seen any confirmatory paperwork on this matter.

Regulatory concerns:

7. It appears that work has been done by the government to ensure the Office for Nuclear Regulation has the authority to oversee UK arrangements for the transport of radioactive materials. Nevertheless, the relevant regulations are not yet available and if a fully operational regulatory system is not available in sufficient time to allow

operators to be compliant at the time of the UK's departure from the EU, this could further delay deliveries of radioisotopes.

Equipment support:

8. The installation, repair, supply of spare parts and calibration of medical devices such as gamma cameras, linear accelerators and PET scanners need the use of calibration and installation kits held at their stores on mainland Europe. These are couriered into and out of the UK. Furthermore, some devices are repaired or calibrated abroad on an infrequent basis and timescales are tight to return them to clinical service. The transport uncertainties and potential customs issues will mean an increased risk of down time compromising service delivery.

Staffing:

9. Medical Physics and Clinical Engineering (MPCE) are suffering from the same recruitment issues as the rest of the National Health Service, with a number of medical physics roles being listed on the National Shortage Occupation List. Still more roles, including those in engineering, meet the criteria for being listed and are under consideration. There are high vacancy rates around the UK, although geographic details vary by specialism. These high vacancy rates are a result of insufficient training capacity during a period of service expansion. Over the last five years continued poor uptake of the Practitioner Training Programme has resulted in few technologists/practitioners entering the workforce, thus exacerbating shortages. We would welcome an expansion of capacity on national training programmes for healthcare scientists but even with an immediate increase, forecasts show these shortages cannot be redressed within less than 3 years for any specialism, with most requiring more than 5 years.
10. In addition, a 2017 survey found that 17.8% of the MPCE workforce originated from overseas, with 9.7% being from the European Economic Area. This illustrates the extent to which the UK is dependent on recruiting from abroad, and we value the ability to recruit from the best in the world. It should be noted, however, that the immigration system at present is not currently optimised to facilitate this, as the salaries paid to needed and highly qualified professionals do not necessarily meet the prescribed minimum. The NSOL listings should mitigate against this but the difficulty of listing an occupation, with infrequent Calls for Evidence, and the inaccuracy of the SOC codes on the list mean that this is far from a failsafe. Response times to visa applications are slow: rapid in this context means days or weeks rather than months.

Research:

11. The UK is a global player in terms of medical physics research and development and has greatly benefited from being a prime beneficiary of research monies through EU funding streams such as Framework 7. This has allowed us to employ the brightest and best researchers from not just the UK, but the EU and the rest of the world. This prime position in medical research is deeply threatened by withdrawal from the EU and would be made much worse by a "hard Brexit".

Drug and device authorisations:

12. As part of the European Medicines Agency (EMA) the UK is seen as part of a larger market. If we are outside the EMA and do not have full reciprocity between the MHRA in the UK and the EMA, (likely to happen in a "hard Brexit") the UK will be seen as a new, small market. This will require the UK to develop its own separate authorization process and as a small market will become a less attractive as a place to introduce new products and services. This will result in the service falling behind in both the short and long term.

Costs:

13. If there is a "hard Brexit" WTO tariffs will apply, which may be as high as 10-30% on any imported goods. It is our understanding, however, that the government can reduce tariffs on certain goods to 0%. It would be hoped that medical equipment, radiopharmaceuticals and radionuclides would be zero rated.

Risk summary:

Risk	Probability	Consequences	Actions required
Compromised Radionuclide and equipment supply	**High**	**Very High**	a) A clear transport and regulatory arrangement b) A clear customs agreement c) Addition resource to accommodate the WTO tariffs
Compromised workforce	**High**	**Medium**	a) A clear facility to attract and maintain staff with high expertise b) Investment in additional domestic training
Compromised clinical and scientific landscape	**High**	**Very High**	a) A clear regulatory infrastructure b) Additional resource to maintain our global research position c) Commercial support to introduce and develop new products

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