

Our Ref: NIRCD/Advisory/2023/0001

26 October 2023

To: HEALTHCARE SERVICES ACT (HCSA) AND PRIVATE HOSPITALS AND MEDICAL CLINICS ACT (PHMCA) LICENSEES

Dear Sir/Mdm

ADVISORY FOR HIGH INTENSITY FOCUSED ULTRASOUND APPARATUS UNDER THE RADIATION PROTECTION ACT 2007

It has come to the National Environment Agency (NEA)'s attention that there are some healthcare institutions who do not have a valid licence from NEA for the possession of High Intensity Focused Ultrasound (HIFU) apparatus.

- In Singapore, HIFU apparatus is controlled under the Radiation Protection Act 2007 and the licences listed below are required:
 - N1 licence: Licence to manufacture or deal with
 - N2 licence: Licence to keep, or possess, for use
 - N4A licence: Licence to import
 - N4B licence: Licence to export
- Any person who imports, exports, keeps, possesses, uses, manufactures or otherwise produces, or sells, deals with, or otherwise deals in any irradiating apparatus without a licence can be charged in court and be liable on conviction to a fine up to \$100,000 or to imprisonment for a term up to 5 years or to both. Any person who fails to give notice of the sale/purchase of any irradiating apparatus to the Director-General or disposes of any irradiating apparatus without approval from the Director-General of Environmental Protection can be charged in court and be liable on conviction to a fine up to \$50,000 or to imprisonment for a term up to 12 months or to both.
- The possible adverse health effects of HIFU on the human body include pain during and after treatment, erythema, edema, bruising and skin burns.
- Please note that HCSA and PHMCA licensees found in possession of HIFU apparatus without a valid NEA licence during MOH inspections may be subjected to non-compliance action. If there is a HIFU apparatus without a valid NEA licence, please immediately cease the usage of the HIFU apparatus and apply for the required licence via the GoBusiness portal at www.gobusiness.gov.sg using your institution's CorpPass.
- For further clarification relating to this advisory, please contact Ms Sim Joo Huang at 6708 6224 or Sim Joo Huang@nea.gov.sg.

Yours faithfully

Ho Seng Kim Deputy Director Non-Ionising Radiation Control Department, Regulation Division Radiation Protection and Nuclear Science Group

[This is a computer-generated letter. No signature is required.]