

Guide to

Applying for a Variation to a Tissue Establishment Authorisation

1 SCOPE

This guide is issued to provide guidance to tissue establishments in applying for a variation to a tissue establishment authorisation.

2 APPLYING FOR A VARIATION TO A TISSUE ESTABLISHMENT AUTHORISATION

Regulation 6 (9) of S.I. No. 158 of 2006 states that 'A Tissue Establishment shall not make any substantial change in the prescribed activities which it undertakes without the prior written approval of the IMB.'

Regulation 6 (10) states that 'Any application by a Tissue Establishment for approval to make a substantial change in its activities must be made in writing to the IMB and accompanied by the appropriate fee.'

Should a tissue establishment or procurement organisation wish to change any detail of their authorisation, the Responsible Person should submit a completed application form to the HPRA, together with the appropriate fee. Please see the 'Publications and Forms' section of www.hpra.ie.

3 GENERAL NOTES

- Variation applications must be submitted **prior** to the authorisation holder implementing the change.
- The only exception to the above is where a Responsible Person or delegate is permanently or temporarily replaced. In this instance the tissue establishment can subsequently but without delay provide the HPRA with the name of the replacement, details of his or her qualifications and the date on which the replacement began their duties. See S.I. No. 158 of 2005, Regulation 8(7)-(9).
- Depending on the variation type, supporting documentation is required as specified in the application form.

- Variations to the tissue establishment authorisation can be classified as **administrative** (requiring a limited amount of assessment by an inspector) or **technical** (requiring significant assessment by an inspector with possible scheduling of a site inspection). The fee required depends on the variation type. The fee code for administrative variations is 330. The fee code for technical variations is 331.
- Following approval of the variation by the HPRA, an endorsed authorisation containing the updated variation will be issued to the authorisation holder indicating the date from which the endorsed authorisation is effective.
- Authorisation holders should retain their original authorisation on file and exhibit the endorsed authorisation as appropriate.
- In certain circumstances, the HPRA may send an e-mail to the tissue establishment to confirm that the variation has been approved. The tissue establishment should attach a copy of the e-mail to their current authorisation until their new endorsed authorisation is issued. Please note that this procedure will only be followed in exceptional circumstances.

4 CONTACT DETAILS

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HPRA
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