Application for Variation to a Blood Establishment Authorisation

*Please ensure all relevant sections of this form are completed to validate your variation application.*

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| section 1: Application details | |
| * 1. APPLICANT DETAILS   Name of blood establishment:  Address of blood establishment:  Eircode:  Date of application:  Authorisation number: | **For internal use only**  Licensing register ref no.:  Endorsement no.:  Fee codes:  CWS reference no.: |
| * 1. RESPONSIBLE PERSON   Name:  Contact address:  Eircode:  Email:  Telephone:  Fax: | |

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| section 2: Proposed variation to the authorisation | | | |
| **2.1 TYPE OF VARIATION**  Please complete a separate application form for each site. Select the appropriate tick-box to indicate the variation being applied for.  Please note that electronic documentation is preferable. If the supporting documents are too large to be sent by email, the HPRA can provide a link to a secure One Drive Sharepoint. | | | |
| **Type of variation**  **A = Administrative T = Technical** | | **Please tick (√)** | **Supporting documentation required** |
| A | Change in name of the authorisation holder |  | 1. Letter confirming change in name. 2. Copy of company registration form or equivalent (if relevant) |
| T | Change in address of the blood establishment |  | If new premises:   1. Letter confirming change of address 2. Copy of company registration form or equivalent 3. Site plan and floor map of new premises 4. Details of suitability of premises and equipment 5. Site Master File or Quality Manual   If administrative change in address:   1. Letter confirming change of address 2. Copy of company registration form or equivalent (if relevant) |
| A | Change in name of site carrying out a prescribed activity |  | Letter confirming change in name |
| T | Change in address of site carrying out a prescribed activity |  | If new premises:   1. Letter confirming change of address 2. Site plan and floor map of new premises 3. Details of suitability of premises and equipment 4. Site Master File or Quality Manual   If administrative change in address:  Letter confirming change of address |
| T | Addition of a Responsible Person to the authorisation |  | 1. Confirmation that new RP meets the requirements of S.I 360 of 2005 2. CV of RP to be added to authorisation |
| A | Deletion of a Responsible Person from the authorisation (if there is more than one listed RP on the current authorisation) |  | Explanation for deletion of Responsible Person from authorisation |
| T | Replacement of a Responsible Person on the authorisation |  | 1. Explanation for replacement of RP 2. Confirmation that replacement RP meets the requirements of S.I 360 of 2005. 3. CV of replacement RP |
| A | Addition of a hospital blood bank supplied by the blood establishment |  | Copy of contract or service level agreement between the blood establishment and the hospital blood bank |
| T | Addition of a new blood component produced by the blood establishment |  | Appropriate validation data |
| A | Deletion of a named blood component produced by the blood establishment |  | Explanation for deletion of named blood component from the authorisation and confirmation that blood component will no longer be produced by the blood establishment |
| T | Addition of a site and/or prescribed activity |  | 1. Site Master File / Quality Manual 2. Appropriate validation data |
| A | Deletion of a site and/or prescribed activity |  | Explanation for deletion of site and/or prescribed activity from the authorisation and confirmation that site will not be used and/or prescribed activity will not be carried out |
| T | Addition of a contractor at which a prescribed activity is being carried out |  | Copy of contract/ service level agreement between the blood establishment and the contractor |
| A | Deletion of a contractor at which a prescribed activity is being carried out |  | Explanation for deletion of contractor from authorisation and confirmation that contractor will no longer be used by the blood establishment |
| T | Change in the prescribed activity being carried out by a contractor |  | 1. Appropriate validation data 2. Updated contract / service level agreement |
| T | Changes in relation to the import and/or export of blood and blood products |  | 1. Details of arrangements in place surrounding the import/export of blood and blood components. 2. Contracts/service level agreements in place with import/export site. 3. Statement by RP that imported/exported blood meets the requirements of relevant legislation   Note: A special condition regarding import/export may be added to the authorisation. |
| T | Other variation to the content of the authorisation. Please specify: |  | 1. Updated Quality Manual if applicable 2. Appropriate validation data if applicable 3. Other information as deemed necessary |
| T | Change(s) at the site(s) at which the blood establishment operates or to the prescribed activities carried out at each site(s) that may impact the quality and safety of blood.  Please specify: |  | Appropriate validation data as relevant  Note: This change may not result in a change to the content of the authorisation but is required to be notified to the HPRA in writing as per Regulation 6 of S.I. 360 of 2005. |
| T | Change(s) which would result in a failure to comply with the requirements of S.I. 360 of 2005.  Please specify: |  | Appropriate justification/explanation for change  Note: This change may not result in a change to the content of the authorisation but is required to be notified to HPRA in writing as per Regulation 6 of S.I. 360 of 2005. |
| T | Change(s) to the quality system that are likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the prescribed activities which the blood establishment has been authorised to undertake as per the terms of the authorisation.  Please specify: |  | 1. Updated Quality Manual or Site Master File 2. Appropriate validation data   Note: This change may not result in a change to the content of the Authorisation but is required to be notified to the HPRA in writing as per Regulation 6 of S.I. 360 of 2005. |

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| **2.2 PROPOSED WORDING**  Please specify the precise present wording in the current blood establishment authorisation and proposed wording underlining or highlighting the changed words.  **(Note: Failure to complete this section may result in the application being deemed invalid.)** | |
| **Present wording** | **Proposed wording** |
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| **2.3 BACKGROUND**  Please give a brief background explanation for the proposed changes to your authorisation (attach additional supporting data as necessary). | |
| **2.4 FEES**  An application fee must be submitted with each request for variation to an authorisation.  Please refer to the ‘Guide to Fees’ onthe ‘Publications and Forms’ section of [www.hpra.ie](http://www.hpra.ie)and complete the fee application form. | |

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| section 3: Declaration |
| I hereby make application for the above authorisation to be varied and/or to notify the HPRA in relation to the above changes in accordance with the proposals given above and certify that the changes will not adversely affect the quality, efficacy or safety of any blood or blood product produced. I declare that amended documents have been supplied and that the supporting information is correct. I declare that all changes have been identified and that there are no other changes in the amended documentation.  I have submitted the appropriate fee as follows:  Per administrative variation - Code 330 Per technical variation - Code 331  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Responsible Person)  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (CEO/Medical Director) |

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