NZBS TERMS AND CONDITIONS RELATING TO EXCEPTIONAL RELEASE OF NON-CONFORMING PRODUCTS

Reason for Issue: To define the two distinct situations where the release of a non-conforming product can be either requested by the treating clinician or initiated by NZBS.

1. POLICY STATEMENT

Non-conforming products pose an additional safety risk to any recipient who receives them.

The New Zealand Blood Service (NZBS) internal policies allow the use of these products only in a life threatening emergency situation and when alternative treatments are unavailable or would be inadequate. In the case of Serum Eye Drops (SEDs) these may be subject to exceptional release as a non-conforming product when there is an immediate risk to the patient's eyesight.

The supply of these blood products is outside NZBS routine supply arrangements. NZBS will follow its internal procedures to ensure the risks of the Non Conforming Product (NCP) are known and possible alternatives are offered and discussed.

The process to release non-conforming product is described below and this policy must be adhered to. The relevant Blood Processing department will release the non-conforming product upon receipt of written authorisation from the Transfusion Medical Specialist (TMS) / Medical Officer (MO). No amendment of these terms will be accepted, and no NZBS employee is authorised to vary or waive the application of these terms if non-conforming blood products are requested.

2. DEFINITIONS

For the purposes of these terms and conditions, unless the context otherwise requires:

"**Clinician**" means the specialist responsible for the immediate care of the patient in the life-threatening situation.

"**Hospital**" means the DHB or Private Hospital employing or contracting with the Clinician.

"**NCP**" means Non-Conforming Product. Non-conforming products are products that have not, at the point where they are issued for clinical use, completed all of the mandatory testing and processing requirements, or the testing and processing is complete and the product fails to meet specification. This may relate to blood products, Haematopoietic Progenitor Cell (HPC) products, SEDs and tissue products (bone and skin).

"**NZBS**" means New Zealand Blood Service.

"**Patient**" means the identified patient who is proposed to receive the NCP.

3. REQUEST FROM DHB AND/OR PRIVATE HOSPITAL SPECIALIST

3.1 Exceptional Release Requested by a Clinician

This policy describes the approach that NZBS will adopt when a request for the supply of NCPs is received from a clinician for treatment of her/his patient. NCP will be issued by NZBS for a designated patient only.
Possible reasons for a clinician to request a NCP include but are not limited to:

- Urgent release of a Serum Eye Drop (SED) preparation that has not completed sterility testing requirements.

- Release of a Haematopoietic Progenitor Cell (HPC) product with incomplete or positive bacterial culture result, or positive virology results.
- Urgent release of a product that has not completed all standard virology testing.
- Urgent release of a specifically collected blood component that has not been subjected to leucodepletion.

When clinicians request exceptional release of NCPs, NZBS will require the clinician to complete a request form before the product is released.

3.2 Clinician's and Hospital's Acknowledgements and Obligations

The Clinician and Hospital acknowledge that:

(a) NZBS will only consider requests for exceptional release of non-conforming products in life threatening clinical situations; or in the case of SED where there is a risk to the eyesight of a patient.

(b) the decision whether or not to use NCP is entirely their own and no reliance has been placed on any representation, written or oral, of NZBS.

(c) they have been advised by NZBS of the risks associated with the use of NCP and of alternative treatments available for the patient that would not require the use of NCP.

(d) there may be risks associated with the treatment of the patient with NCP that NZBS may not be aware of or may not have identified, as well as other adverse reactions arising from the use of NCP that are unknown to NZBS.

(e) there may be alternative treatments that NZBS may not be aware of or may not have identified.

(f) it is the Clinician's responsibility to consider all available treatment options for the patient.

(g) they accept full responsibility to obtain all necessary consents to the use of NCP and otherwise comply with the Code of Health and Disability Services Consumers' Rights.

The Clinician and Hospital warrant that they shall only use the NCP on the designated patient.

The Clinician warrants that, in his/her considered opinion, having taken into account the acknowledged risks, the use of the NCP is justified by a life-threatening emergency that confronts the patient (or in the case of SED an unacceptable risk to the patient's eye/s).

The Clinician shall sign the NZBS release form whenever s/he requests NCP.

4. EXCEPTIONAL RELEASE INITIATED BY NZBS

This policy also covers situations where NZBS is unable to provide routine products that meet specification and due to an urgent clinical need must release NCP. NCP will be issued by NZBS for a designated patient only.

Possible reasons for NZBS to release an NCP include but are not limited to:

a) Urgent release of a platelet component prior to 36 hours having elapsed since collection i.e. before routine sampling for bacterial culture has been undertaken.

b) Urgent release of a product that does not meet all specified manufacturing requirements, e.g. a matched platelet preparation in which the number of platelets is below the minimum specification approved by MedSafe.

If NZBS is required to release a NCP, the requesting department must obtain approval from the TMS / MO. The TMS / MO will discuss the risks and alternatives with the clinician and record the clinician's decision to accept the NCP.

All instances of early sampling and release of platelet components, as described above in (a), must be reviewed subsequently by the Area Manager. The purpose of the review is to identify strategies for minimising and avoiding the early release of non-conforming platelet components in future.

All instances of early sampling and release of platelet components initiated by NZBS will be reviewed by CAG.

4.1. Acknowledgements and Obligations by NZBS

- NZBS shall identify and advise the Clinician on the risks associated with the NCP requested and shall use its best endeavours to identify and discuss other treatments that may be available for the patient without the use of NCP.
- Where applicable NZBS shall as soon as possible test the NCP used in accordance with its standard procedures.
- NZBS shall notify the Clinician in the event that any post release testing indicates that NCP released is shown to be reactive / positive.
- NZBS reserves the right not to release NCP unless satisfied that the Clinician has properly and responsibly considered the risks and alternatives and that the situation is life threatening.