EXCEPTIONAL RELEASE OF NON-CONFORMING PRODUCT

Reason for Issue: To define the two distinct situations where the release of a NCP can be either requested by the treating clinician or initiated by NZBS, DCR8799 add the requirement to send a copy of the completed form with Non-Conforming Products (NCP) at issue, update formatting, DCR18279 & 19235 add reporting requirements in Section 6, change document title, DCR20011 add the location of 150F089 Release of Non-Conforming Products Register, DCR19917 remove references to blue expiry labels

1. PURPOSE

To ensure that exceptional release of NCPs is carried out only after all other options have been investigated and the requesting clinician has been fully informed of the risks.

2. SCOPE

This is an NZBS national procedure; it applies to the issue of all blood components, Serum Eye Drops (SED), Haematopoietic Progenitor Cell (HPC) or tissue products that do not meet the required standard, irrespective of the reason.

The release of an NCP can be initiated by the treating clinician e.g. urgent release of a Serum Eye Drop (SED) preparation that has not completed sterility testing requirements. The exceptional release of a non-conforming platelet component may be initiated by NZBS in situations where a routine product that meets all manufacturing specifications is not available e.g. urgent release of a matched platelet prior to 36 hours having elapsed since collection.

3. KEY RESPONSIBILITIES

The Transfusion Medicine Specialist / Medical Officer (TMS / MO) is responsible for timely consultation with the treating clinician regarding the exceptional release of NCP and for authorising its release.

In those situations where the treating clinician has requested the release of NCP it is his/ her responsibility to complete the applicable sections of the related forms after discussion and consultation with NZBS TMS / MO.

Where NZBS has initiated the exceptional release of a non-conforming platelet component the TMS / MO at the site where the patient is situated (local TMS / MO) will authorise the release after contacting the treating clinician. When this relates to release of a platelet component prior to routine bacterial sampling the Area Manager is responsible for reviewing the decision to release as a NCP at the earliest opportunity in order to determine the reason a routine product that meets specification was not available.

4. DEFINITIONS

An NCP is a blood component, SED, HPC or tissue product that does not, at the time of issue, fully comply with current NZBS standards. This includes product for which mandatory testing has not been completed.

5. DOCUMENTS

5.1 Required Documents

- All available information on the component / products to be issued.
- 111F019 Request from Treating Clinician for Exceptional Release of Non-Conforming Products
- 111F024 Exceptional Release of Non-Conforming Platelet Component
- 150F029c Request for Exceptional Release of Non-Conforming Serum Eye Drops
- 111P019 NZBS Terms and Conditions Relating to the Exceptional Release of Non-conforming Products.
- 151M033 Issue and Return of Cellular Therapy Products
- 110F561 Record of Manual Stock Transfers/Bulk Distribution
- 150F089 Release of Non-Conforming Products Register

6. PROCEDURE

6.1 Exceptional Release Requested by a Clinician

6.1.1 NZBS TMS / MO:

6.1.1.1 Upon receipt of a request for a non-conforming product, confirm with the treating clinician that it is absolutely necessary to use the non-conforming product and that failure to do so would be considered life threatening, or in the case of SED; failure to use them would pose a risk to the patient's eyesight.

6.1.1.2 If no standard product is available forward 111F019 (or 150F029c in the case of SED) to the requesting clinician. Discuss with the treating clinician:

(a) Extra risks associated with the NCP.

(b) Any other standard alternative that may be available.

(c) The terms and conditions upon which the NCP is released and ascertain that they are clearly understood and agreed to as per 111P019.

(d) That the request must be in writing and that the product can only be released upon receipt of 111F019 or 150F029c (Section One completed).

6.1.1.3 It is the responsibility of the treating clinician to obtain informed consent from patient / guardian / representative of the patient for using the NCP (this statement appears in the declaration to be signed by the requesting clinician).

6.1.1.4 Upon receipt of 111F019 or 150F029c from the requester, complete Section Two then forward to the relevant Blood Processing department to release the NCP. In the event that approval is denied record the rationale in Section Two.

6.1.1.5 Inform the requesting clinician of the outcome of testing of the products involved via the completed 111F019 or 150F029c.

6.1.2 Blood Processing:

6.1.2.1 Include a copy of 111F019 (Sections One and Two completed only) with non-conforming HPC (refer to 151M033 Issue and Return of Cellular Therapy Products) or blood products at the time of depot move or issue (use 110F561 Record of Manual Depot Transfers when performing a manual depot move e.g. in the case of an urgent granulocyte). It may be helpful for Clinical staff (HPC) or Blood Bank (other components) to be aware that the product is non-conforming. Forward a copy of 150F029c (Sections One, Two and part of Section Three completed) to the requesting ophthalmologist when releasing SEDs as a non-conforming product.

6.1.2.2 Following release of the NCP ensure all testing is completed, update the relevant form and forward to the TMS / MO.

6.1.2.3 Update 150F089 Release of Non-Conforming Products Register at V: Blood_Processing \ 150F089.xlsx. Present updated information for review and discussion at the regular Management Review Meeting.

6.2 Exceptional Release of Non-Conforming Platelet Component Initiated by NZBS

6.2.1 Requesting Department

- Complete Section One of 111F024 Exceptional Release of Non-Conforming Platelet Component providing the justification for the request and the details of the non-conformance.

- Obtain authorisation from the *local* TMS / MO via 111F024. Requests from Palmerston North will be reviewed and authorised by the TMS / MO in Wellington.

- If it is out of office hours and you have contacted the on-call TMS / MO by telephone, record the verbal authorisation on 111F024. Forward to the TMS / MO during office hours for his / her signature.

- Inform the Area Manager of the request without delay.

6.2.2 NZBS TMS / MO:

- Contact the treating clinician to discuss the risks of and alternatives to the use of the NCP.

- Ensure that the terms and conditions upon which the NCP is released are clearly understood and agreed to as per 111P019. Obtain the treating clinicians consent for the use of the NCP for his patient.

- Ensure that the treating clinician understands his responsibility to obtain informed consent from the patient / guardian / representative of the patient for the use of the NCP.

- Complete Section Three of 111F024, and return to Blood Processing.

6.2.3 Blood Processing

- Upon receipt of the authorisation to release the NCP, complete sampling for bacterial contamination of the platelet per routine procedures.
- Reduce the expiry to five days.
- Include a copy of 111F024 with the NCP at the time of depot move as it may be helpful for Clinical and Blood Bank staff to be aware that the product is non-conforming.
- Following release of the NCP ensure all testing is completed and update 111F024.
- Update 150F089 Release of Non-Conforming Products Register at V:Blood_Processing \ 150F089.xlsx.and forward 111F024 to the Area Manager for review. Present all events of the release of non-conforming products at the regular Management Review Meeting.

6.2.4 Blood Bank

- Record the details of the patient transfused on 111F024 and forward to the originating Blood Processing department.
- If the non-conforming product is not transfused to the patient recorded in Section Two, return the non-conforming product to the originating Blood Processing department.

6.2.5 Area Manager

- Review the issue of the non-conforming product at the earliest opportunity. The purpose of the review is to determine whether a standard product could have been released and whether any changes to inventory or procedures may be required to minimise the need to release non-conforming products in the future.
- Complete Section Five of 111F024.

7. MINIMUM TRAINING REQUIREMENTS

☐	Complete Document Sign-Off Sheet (108F060). • Read specified sections: Sections: *(enter section numbers)*
✓	Complete Document Sign-Off Sheet (108F060). • Read and understand whole document
☐	Complete Document Sign-Off Sheet (108F060). • Formal training required
☐	Complete Training Module *(enter name of module)*
☐	No training required. Specify reason: