



PZQ2
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Request management at CeRBIM

PRC-P1-CRB-004

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A-Purpose and field of application

This procedure describes the organisation defined for the management of any request made to CeRBIM.

B. Reference documents

Standard NF EN ISO 20387: General requirements for biobanking

ISO 9001 standard: Quality management system - Requirements

C. Responsibilities

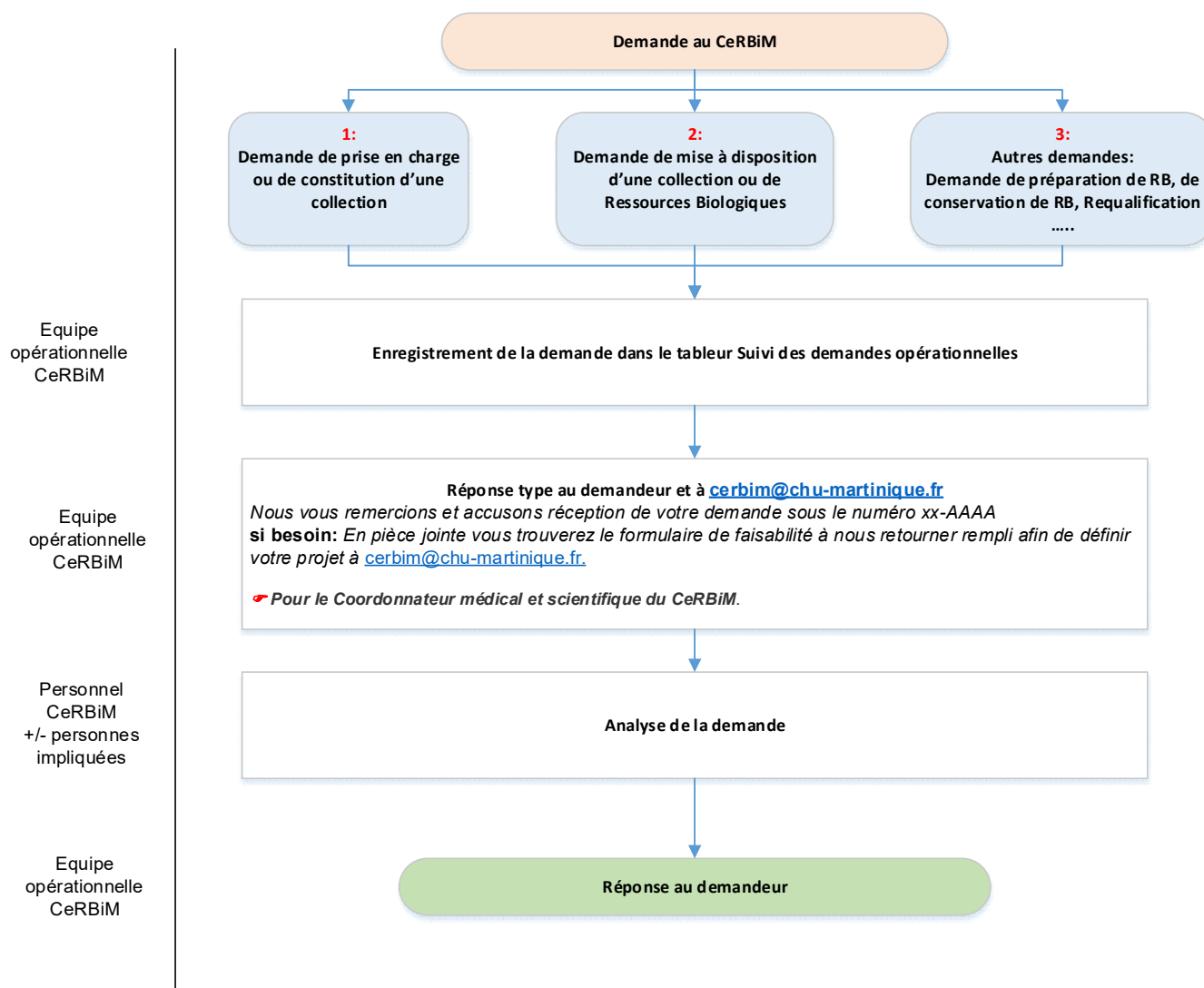
The CeRBIM coordinator is responsible for applying this procedure.

The quality manager ensures that the document is kept up to date.



D-Description of the procedure

D-1 Operational requests



- ➔ All operational requests are :
- recorded and the actions traced in the "Follow-up of operational requests" spreadsheet
 - analysed as a team
 - discussed +/- with the people involved
 - submitted to the weekly team meeting with the coordinator for approval

- ➔ For industrial applications: organise a meeting with DRCI to discuss regulatory issues

D-2 Other requests

- ➔ Request related to a study: finance, monitoring, other
Request communicated to the team and tracked in the study file
- ➔ Requests for information, complaints, other :
- Discussed at a meeting
 - Traced, depending on the subject, in the server's reports **and/or** operational file **and/or** in accordance with the non-conformity management procedure **and** recorded via the EDM.

E. Related documents

Via Kalilab