MINISTRY OF PUBLIC HEALTH

Reorganization of Blood Transfusion process in Lebanon

Specifications of the medico-technical software

Established in collaboration with

ESA

EFS

ÉTABLISSEMENT FRANÇAIS DU SANG

Specifications of the medico-technical software

The specifications process is two-fold :

- Definition of software specifications
- Definition of hardware requirements.

The below specifications only cover the software specifications.

Description of features

A. General software characteristics

When the medico-technical software is introduced, a set of services is required to perform the handover and ensure autonomy and independence for the client vis-à-vis the supplier. The supplier must commit to retrieving the data history of donors, donations and recipients and integrate it into the new database.
The main steps of the installation project are as follows:

- Server and operating system installation
- Database installation
- Loading of the basic configuration in the database
- Configuration training
- Configuration support
- Configuration definition
- Actual configuration
- Design of test scenarios
- Validation of data recovery
- Configuration validation
- Installation of workstations
- User training and validation of use on different stations
- Assistance at the first use.

1. The blood bank management database must include, at least, the following modules :

   - Home, administration and management of blood donors and samples
   - Managing fixed and mobile collection points
   - Managing the preparation of labile blood products
   - Managing the biological qualification of donations
   - Managing recipient immunohaematology
   - Managing the delivery of labile blood products
   - Stock management
   - Managing the monitoring of traceability and vigilance (hemovigilance, reactovigilance, materiovigilance)
   - Billing
2. Graphical interface
3. Password-restricted access
4. Encrypting of passwords stored in database
5. Configurable password expiry and renewal
6. Allocation of access rights to features for user profiles
7. Configurability of the software

8. Traceability of users who perform a given operation
9. Number of maximum workstations supported by the proposed configuration
10. Connections with machines to be ensured as well as interfacing with all laboratory software.
11. Documentation, user's guide, configuration guide, command description, index of available error messages

B. Detailed functions of modules

I. BLOOD COLLECTION

Administration of donors

12. Automatic numbering of new donors
13. Control of number keys with dismissal of incompatible format numbers
14. Verification of entered dates and their consistency in relation to the current date
15. The donor number shall be unique and cannot be re-used
16. Entry of configurable administrative information for each donor
17. Entry of medico-technical data configurable for each donor
18. Generation of views on donors displaying only selected information
19. Availability of a program to merge donor records according to configurable terms and rights
20. Ability to perform criteria-based selections, based on administrative and medico-technical data of donors
21. Donor identification through a configurable number of identifiers
22. Ability to search for names, not only based on similar names or prefixes, but on names with identical or similar pronunciation (lexical and phonetic search)
23. Filtering of donors according to configurable criteria: date of birth, names ...
24. Periodical retrieval of the list of donors that have changed since the last extraction
25. Generation of automatic alerts to the donors home page according to fully customizable criteria
26. The secretariat shall have access to a customizable and limited part of the donor record and donations, upon arrival of the donor

Organizing blood collection

27. Management of blood drive schedules
28. Publication of a summary data sheet on a specific collection point
29. Publication of a fully customizable history of previous sessions for a given collection point or set of collection points
30. Module for the management of human and material resources needed for a given collection point
31. Publication of fully customizable consistency slips at the end of the collection

Medical care and homologous blood collection

32. Automatic numbering of donations with key control and consistency check
33. The donation number shall be unique and cannot be reused. It should be linked to the donor number

34. Publication of a collection sheet where the customizable content includes the unique donor number
35. Suggestion of a customizable standard questionnaire to the person in charge of the medical interview
36. During the medical interview, the interviewer shall have access to the entire records of the donor and his donations
37. Ability to set the procedure to be followed after the medical interview
38. Ability to offer default collection instructions, where the content and the form are fully customizable
39. Management of donors with no donations
40. After sampling, publication of a blood bag label, of fully customizable shape and content

Autologous donations

41. For the management of autologous donations, entry of customizable patient information, prescription and tests to be performed or completed, upon initialization of each new protocol
42. Generation of an autologous donation number with similar security guarantees provided to the homologous donation
43. Customization of an autologous transfusion protocol, including the characteristics of samples to be taken and their programming
44. Automatic protocol closure after completion of the last scheduled collection
45. At the end of the protocol, publication of a customizable letter to various external parties

II. PREPARATION OF LABILE BLOOD PRODUCTS

46. Processing of blood bags by barcode and / or manually with consistency check with the collection data
47. Automated and fully customizable management of the receipt of blood bags
48. Management of non-compliance according to fully customizable criteria, upon receipt of blood bags
49. Upon receiving each blood bag, the publication of a document of fully customizable content and form, to track all preparation operations
50. Determination of the labeling requirements for labile blood products, as to the label content and form
51. Registration of all operations of production, transformation, and handling in a completely configurable manner, for a list of characteristics of each labile blood product by the end of production
52. Ability to track equipment and materials used for production
53. Ability to trace the signature of production operators for all indicated operations
54. Access to the donor history based on their donation number, where the history cannot be modified
55. Definition of decision trees based on product characteristics: collection volume, storage time before processing ...
56. Automatic (or manual) quarantining of a product, pending a medical decision, under certain configurable conditions
57. Quarantine follow-up from raw material to finished product

58. Statistical views of the prepared products
59. Management of the expiry date and time of for all prepared products
60. At each step of the labeling procedure, the software shall ensure that the read barcode is the one expected, by controlling "starts and stops" (or barcode identifiers in the case of ISBT 128)
61. Ability to manage the separation of a product into several products and ensure their monitoring and traceability
62. Ability to manage all product mixtures and ensure their monitoring and traceability
63. Ability to manage all types of product processing
64. Ability to manage the re-labeling of individual, mixed and processed products
65. Ability to configure complementary tests performed during preparation on certain products and the blocking conditions
66. Ability to set specific labeling rules for autologous products
67. Ability to edit a listing of labeled products
68. Management of the composition of quality control samples for the labile blood products
69. Management of quality control analyses carried out on products
70. Link to donor folders from the preparation phase
71. The software shall allow to customize the management of product quarantining and securing operations
72. When configuring a secured product, the administrator shall be able to specify certain information
73. The software shall allow to set alerts and terms of product blocking and unblocking
74. The software shall allow to customize the tracking and traceability of all product destruction operations

III. **BIOLOGICAL QUALIFICATION OF DONATIONS**

75. Fully configurable automatic generation of applications for tests associated with sampling tubes
76. Ability to enter or import the sampling characteristics from the collection station.
77. In case of manual entry, ability to perform double entry of tubes with consistency check
78. The software shall allow the publication of documents containing the list of tests to be performed and on which results should be manually reported
79. Definition and management of the automation of data exchange between the laboratory and other equipment and machines
80. The terms for technical validation of the results should be configurable
81. The software shall help secure the manual entry of laboratory results through the use of configurable tags
82. The software shall allow to configure whether entries of the same test should be performed by different users
83. The software shall allow to configure whether a history check is needed for each exam
84. The software must allow for specific configurable management of internal and external quality controls
85. The software shall allow to identify and configure the conditions for biological validation of results
86. The software shall allow to report tests on future samplings from the donor

87. Result publication must be fully configurable
88. The software shall allow for sorting and publication of statistical reports based on various configurable criteria
89. The software shall allow the inclusion of all traceability data assigned to a test result
90. The software shall allow traceability of equipment, reagents, and consumables used for a given analysis
91. For a specific laboratory result, the software shall allow to set alerts, emails or a list of medical contra-indications for the donation
92. The software shall allow for the publication of a first donation letter and a donor card according to configurable criteria
93. The software shall allow to automatically take into account the laboratory results as part of the medical follow-up of donors
94. The software shall allow to automatically take into account the laboratory results in the process of blood product preparation, as they become available
95. The software shall allow the configuration of a list of manufacturing incidents related to biological qualification
96. The management of indeterminate results should be configurable
97. Ability to electronically block donations according to several configurable biological criteria
98. Ability to statistically use all the qualification data
99. Ability to customize the issuance of a blood bag label after qualification

IV. RECIPIENT IMMUNOHAEMATOLOGY

100. Ability to customize the entry of administrative and medico-technical information relevant to the demand for tests
101. Ability to customize the entry of sampling-related information
102. Ability to customize the issuance of a single secure internal patient number for the blood transfusion center
103. Ability to customize the issuance of a single secure internal sampling number for the blood transfusion center. Such a number shall be linked to the internal patient number.
104. Patient identification shall be available in several customizable options.
105. Ability to customize the entry of all type of requested testing: simple, consolidated, in packs…
106. Ability to perform a double entry of requested tests, with consistency check of the data entered
107. The software shall allow to define conditional testing
108. The software shall allow to manage reported examinations from previous sampling
109. The software shall control analysis redundancy
110. The software shall define and manage the automation of data exchange between the laboratory and other equipment and machines
111. The software shall allow the publication of documents containing the list of tests to be performed and on which results should be manually reported
112. The terms for technical validation of the results should be configurable
113. The software shall help secure the manual entry of laboratory results through the use of configurable tags
114. The software shall allow to configure whether entries of the same test should be performed by different users

115. The software shall allow to configure whether a history check is needed for each exam
116. The software must allow for specific configurable management of internal and external quality controls
117. The software shall allow to identify and configure the conditions for biological validation of results
118. The software shall allow to report tests on future samplings from the donor
119. Result publication must be fully configurable
120. The software shall allow the inclusion of all traceability data assigned to a test result
121. The software shall allow the publication of a group card according to configurable criteria
122. The software shall allow to automatically take into account the laboratory results in the recipients' transfusion file
123. Ability to statistically use all recipient immunohematology laboratory data
124. The software shall allow to keep track of inpatient stay for each patient, along with the names of each healthcare facility
125. The software shall allow to adjust the number and quality of recipients of the analysis results
126. Availability of a configurable function for external result entry that can be enabled or disabled by the system administrator
127. Possibility of simultaneous entry of product prescription after entry of the test results
128. A published analysis result should be able to be reissued with a similar time stamp, even after a technical and / or setting change
129. Electronic submission of test results to healthcare facilities in standardized form.

V. DELIVERY OF LABILE BLOOD PRODUCTS

130. Ability to manually enter prescriptions, with consistency check for entered data
131. Ability to control delivery compliance after prescription entry with a customizable proposed course of action
132. Ability to configure the issuance of a single secure internal prescription number for the blood transfusion center linked to the patient number
133. For each prescription, availability of customizable administrative and medico-technical information
134. Patient identification according to configurable criteria
135. Lexical and phonetic search feature for patients
136. After patient identification, display of full transfusion file, if applicable
137. Allow the setting of mandatory information to be introduced for each product
138. Enabling of configuration in the transfusion protocol delivery module
139. Possibility to integrate the management of transfusion protocols into the entry of prescriptions
140. Possibility to configure the management of protocols and autologous prescriptions
141. When prescribing autologous products, ability to configure the control of homologous product prescription
142. Ability to obtain a proposal of the best products available to the patient during the product attribution phase based on configurable criteria
143. Users allowed to publish a configurable list of suggested products
144. Immediate or delayed attribution of products to be configurable in software
145. Ability to configure an unlimited number of distribution rules

146. Ability to configure the attribution rules and conditions in life emergencies
147. The software shall allow the configuration of the mother-child connection management
148. At the completion of product attribution, the software shall allow for registered labeling of attributed products and the issuance of an attribution slip of configurable form and content
149. The immediate or deferred product delivery shall be fully configurable
150. At the end of the delivery, the software shall allow editing of documents required by regulation
151. The software shall allow the management of delivery hours and cut-off time for returns
152. The software shall allow the configuration of the entry of delivery sheets completed by healthcare facilities
153. The software shall update the patient transfusion records by entering all delivered products
154. The software shall allow the issuance of fully configurable transfusion statistics
155. The software shall allow the tracking of all delivery operations
156. The software shall allow the setting of the cancellation policy of a prescription, an allocation or a delivery and the processing of return products
157. When processing product returns, the software shall allow to set the course of action for these products, according to introduced or automatically generated criteria
158. When processing product returns, patient records shall automatically be updated
159. The software shall allow to merge patient records according to configurable criteria

VI. STOCK MANAGEMENT

160. The conditions of entry and exit of products shall be fully configurable
161. In case of manual entry of products, the software shall increase the reliability of double entries or barcode entries
162. The software shall allow product management from several warehouses and stocks
163. The software must provide the ability to admit into stock products from external sites without polluting the donor file
164. The software shall allow the issuance of a single attribution number for non-personal attributions between sites and their warehouses
165. The software shall allow to set the validity, monitoring and traceability of transportation
166. The software shall allow to set the conditions and product session supports
167. The software shall allow users to view the stock according to conditions calculated based on set criteria
168. The software shall allow the setting, definition and monitoring of target stock levels for each site
169. The software shall allow to set the conditions, steps and supports for the transfer of goods between different sites
170. Inter-site product transfer operations shall be traced in the history of operations for each product
171. The software shall allow to set the conditions and supporting for product reservation or cancellation

VII. MONITORING OF TRACEABILITY AND VIGILANCES

172. Based on the number of the donor, donation or sampling, the software shall allow to find all information relating to the collection and the status of derivatives

173. Based on the product number, the software shall allow to find all the information about the donor, donation and products from the same donor and the same donation
174. Ability to initiate and pursue transfusion investigations
175. Ability to customize the management of transfusion incidents and proposed course of action
176. Ability to generate statistical reports about transfusion incidents, according to configurable criteria

VIII. BILLING

177. The software shall allow the management of billing of tests and homologous and autologous products distributed by name
178. The software shall allow the management of billing of tests and homologous and autologous products distributed in bulk to blood banks and/or other blood transfusion centers
179. The software shall allow the management of product returns after billing
180. The software shall allow automatic recovery of billable items of the medico-technical module
181. The software shall allow the archiving of customer information and rates