



e-Network Forum

CALIFORNIA BLOOD BANK SOCIETY

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Supplier Qualifications and Blood Product Label Verification

A blood banker in Maryland would like to know how others in the e-network forum are **getting information from their vendors on supplier qualifications**, and how other blood banks are handling **label validations**? The inquiring blood banker has requested each supplier to complete a self-survey that outlines applicable licensing information and customer service policies. The questions of the self-survey coincide with the inquiring blood banker's supplier qualification criteria as defined in her facility's SOP. The inquiring blood banker's lab uses a chart that plots each supplier's attributes against the defined criteria. For label validation, the inquiring blood banker has contacted label suppliers for the information that qualifies them as a vendor to supply blood bank regulated labels. Finally, the inquiring blood banker's lab has an SOP that requires each new shipment of labels to be checked for compliance and to be compared to the previous label in use.

The inquiring blood banker would appreciate any **additional information or recommendations** from the blood bank community.

Before broadcasting this discussion, **input was sought from experts within the AABB**. According to that response, the AABB does not prescribe a specific recommended method; each facility should determine what works best for them in achieving the required goal. However, the **AABB does provide examples** for the blood banking community of what might be considered appropriate to implement. For one such example, please see the following excerpt from the Standards Source, which can be purchased by going to the [AABB web site](#) and following links to the AABB marketplace, the AABB bookstore, to order on-line. Below is an example of the content of the **Standards Source** as it pertains to this particular e-network forum discussion:

4.1 Supplier Qualification

The blood bank or transfusion service shall evaluate and participate in the selection of suppliers prior to acceptance of an agreement.

Question: Our institution has been using the same reagent supplier for 10 years and we haven't experienced any problems. Can we continue to use this supplier without going through the supplier qualification process?

Answer: It is acceptable to "grandfather" some current suppliers who are known to perform satisfactorily; however, the facility should have a process in place that continues to evaluate the qualifications of the supplier. When qualifying suppliers, either new or current, the blood bank or transfusion center should define which materials and services are considered critical. For non-critical products, a review of references may suffice. Critical products, such as anticoagulants, however, would require a more extensive supplier qualification process.

The term "**supplier**" is defined as an "individual or organization that provides an input material or service" to the blood bank or transfusion service, and can include other departments within the same facility. The blood bank or transfusion service is required to ensure that materials or services obtained from the supplier, which are acquired or incorporated into its blood and components, are acceptable.

Acquired materials and services include those that are purchased, donated, or otherwise obtained. They include, but are not limited to, blood, components, blood bags, test kits, and reagents. Examples of services include infectious disease testing, equipment calibration, and transportation.

Once the critical suppliers are defined, they should be obtained from suppliers qualified by the facility. **Examples of supplier qualification factors include:**

- Licensure, certification, or accreditation by a reputable organization
- Product requirements
- Review of a supplier's relevant quality documents
- Review of the institution's experience with the supplier
- Cost of materials or services
- Delivery arrangements

- Financial security, market position, customer satisfaction
- Post-sales support

The **following concepts are integral to ensuring incoming products and services are controlled**. The blood bank or transfusion service should:

1. Determine the **criteria** that will be used to evaluate each supplier's acceptability.
2. Ensure that the potential **supplier is capable of consistently meeting** the institution's requirements.
3. Determine the **type and extent of control** the blood bank or transfusion service needs to exercise over the supplier. Suppliers may require less control with licensure, accreditation, or certification by reputable organizations (e.g., FDA, CAP, and AABB).
4. Maintain a **list of approved suppliers** of critical materials and services. A policy requiring purchasing personnel to use only these suppliers should be in place.
5. Maintain **records of a supplier's failure** to meet requirements. Deviations, rejections, and complaints should be brought to the attention of the supplier, for their corrective action, and to management with contracting authority.
6. Perform and **document periodic review** of agreements and evaluations of the supplier's performance (e.g. annually or every 3 years).

Supplier qualification does not eliminate the need to validate a particular critical material or service for use in the facility's processes and procedures.

The AABB is aware that many institutions make purchasing decisions for the entire organization. In these situations, it is recommended that **individual departments educate the administration with contracting authority on the importance of qualifying suppliers**. Reporting the failures of suppliers to meet requirements, and recording these initiatives, will provide evidence that the department is striving to meet this Standard. During a management review of the quality system, these failures will be revealed and may give the department more leverage in the supplier selection/qualification process.

Finally, regarding **label validation**, one possible approach would be for a facility to apply a generic validation concept to labels. Check that they perform as expected. The responding expert believes that most labels have a bar code. Aside from reviewing the text to be sure it reflects the text that was ordered, the responding expert would verify the bar code reads accurately in the computer system.



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Please submit comments to the [e-Network Forum](#).

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CBBS e-Network Forum Editor & Moderator

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Addenda: