



Advancing Transfusion and  
Cellular Therapies Worldwide

31 May 2016

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Submitted via <http://www.regulations.gov>

**Re: Docket No. FDA-2016-N-0406**, “Medical Devices; Hematology and Pathology Devices; Classification of Blood Establishment Computer Software and Accessories” proposed rule, 01 March 2016.

Dear Dockets Manager:

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

We appreciate the opportunity to provide comments to the Food and Drug Administration (FDA) on the proposed rule titled “Medical Devices; Hematology and Pathology Devices; Classification of Blood Establishment Computer Software and Accessories.” These recommendations and comments on the proposed rule were prepared by the member experts of AABB’s Information Services Committee, with input from members, National Office subject matter experts, and reviewed and approved by the AABB Board of Directors.

AABB agrees with the FDA’s proposed classification of the blood establishment computer software (BECS) and BECS accessories into class II (special controls) with the 510(k) clearance requirements for manufacture and validation in the user’s facility unchanged. AABB agrees that the proposed special controls, in addition to general controls, would provide a reasonable assurance of the safety and effectiveness of BECS and BECS accessories. AABB also agrees that this would mitigate the risks to patients of transfusion reaction, death, and transmission of infectious disease as well as risks to the health and safety of donors.

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AABB agrees with the Blood Product Advisory Committee's Device Classification Panel (the Panel), and believes the definition of BECS accessories must be sufficiently clear to enable industry to apply the requirements as intended by FDA. Consistent with the view of the Panel, AABB recommends that FDA **clarify** which added functionalities would be considered a BECS accessory and, therefore, subject to regulations as a class II device with special controls. Specific recommendations follow to address these concerns.

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Comments to specific proposed requirements are arranged in the following format:

**Section** – language from proposed rule reprinted.

**Recommendation or Request for Clarification** – recommendation or clarification request.

**Rationale/Supporting Information** – rationale in support of the recommendation /clarification request.

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## **Section**

### **§ 864.9165 Blood establishment computer software and accessories.**

(a) Identification. Blood establishment computer software (BECS) and BECS accessories are devices used in the manufacture of blood and blood components to assist in the prevention of disease in humans by identifying ineligible donors, by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis, by performing compatibility testing between donor and recipient, or by performing positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions. A BECS accessory is intended for use with BECS to augment its performance or to expand or modify its indications for use.

### **Request for Clarification**

As referenced above, §864.1965(a) identifies a BECS accessory and its intended uses. FDA's proposed identification of a BECS accessory is not sufficiently precise. AABB requests specific detail sufficient to appropriately distinguish between the many devices that are currently used by blood establishments rather than broadly capture devices posing less risk which do not require classification at the level of Class II (special controls). AABB believes many devices and applications currently used in daily operations are not BECS accessories based on the proposed language of **§864.9165(a)**, reprinted here, regarding the intended use:

- ...in the manufacture of blood and blood components to assist in the prevention of disease in humans by identifying ineligible donors, by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis, by performing compatibility testing between donor and recipient, or by performing positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions.
- And with BECS to augment its performance or to expand or modify its indications for use.

AABB notes that, rather than remain silent on the scope or regulations, additional discussion of intent and scope with a clear and precise definition of BECS accessories will contribute significantly to the protection of the health and safety of donors and transfused patients by assisting industry:

- To improve understanding of the intent and scope of the new regulations, and
- To effectively mitigate risks through effective compliance efforts.

**Rationale/Supporting Information**

The basis for AABB’s comments is more easily understood if applications are “categorized” in this justification for the purpose of illustrating the differences in purpose, function, and risk.

1. BECS accessories– A software application, software interface or electrical hardware device that determines an outcome (result) that augments the performance of a BECS by providing data that is used by the BECS (for its intended use) to determine donor eligibility.

AABB believes BECS Accessories:

- Are software applications or interfaces that allow the electronic transfer of information with the intent to add, update or delete data by point-to-point connection (including wireless) to a BECS.<sup>i</sup>
- Electrical hardware device that determines an outcome (result) when integrated with a BECS, and together they function as a system to prevent collection and release of unsuitable blood.
- Are appropriately regulated as part of the BECS, requiring 510(k) clearance from FDA.
- Are not considered Medical Device Data Systems (MDDS) but a MDDS that provides data to a BECS should be regulated as a BECS accessory<sup>ii</sup>.

**Recommendation**

AABB recommends FDA distinguish a BECS accessory from MDDS and other utilities following the key concept that **a BECS accessory provides data “to a BECS” to enable the BECS to perform according to its intended purpose**, i.e. to control donor eligibility or product quality determinations to assist in the prevention of disease in humans by identifying ineligible donors, by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis, by performing compatibility testing between donor and recipient, or by performing positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions.

**Rationale/Supporting Information**

The basis for AABB’s comment is that the proposed rule should make it clear that *data flows from an accessory to the BECS*, and an application or interface that transmits data to a BECS that is unrelated to the intended use of a BECS is not a BECS accessory.



We believe the definition of BECS accessory encompasses a range of interfaces from various devices while permitting the effective use of technology in blood collection, manufacture, and

distribution. We recommend the definition includes an interface from another medical device to a BECS that can provide as few as one or two data elements.

For example, something as simple as an interface from a blood pressure cuff which augments the performance of the BECS by providing data that is used by the BECS to determine donor suitability.



An interface between two BECS systems that transfers data related to intended use should also be considered a BECS Accessory.

The elements of a BECS accessory defined above are straight forward and easy to understand. These criteria should be used by FDA to provide clarity in the definition of BECS accessory necessary to protect the health and safety of patients and donors.

## 2. MDDS:

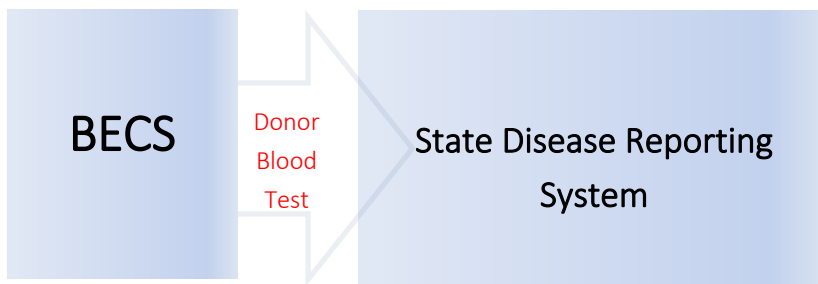
### **Recommendation**

AABB disagrees with the proposed definition for a BECS accessory because it does not specifically exclude data that is extracted *from the BECS for use by other applications* that are unrelated to donor eligibility and blood product quality decisions performed by a BECS. More specific information is needed to properly interpret “...to augment its performance or to expand or modify its indications for use.”

### **Rationale/Supporting Information**

The proposed rule should exclude data that is interfaced from the BECS to donor scheduling and reporting systems, HIS, LIS, patient management systems and disease reporting systems. Interfaces that export patient and product data are more appropriately classified as MDDS. Interfaces that export donor test results for state disease reporting should also be classified as MDDS.

Clearly, a system that uses data from the BECS to make additional donor eligibility or product decisions is a BECS itself.



A MDDS is a Class I medical device that can interface, extract or use data from the BECS and should remain a MDDS as identified and *consistent with current regulations reprinted here*:

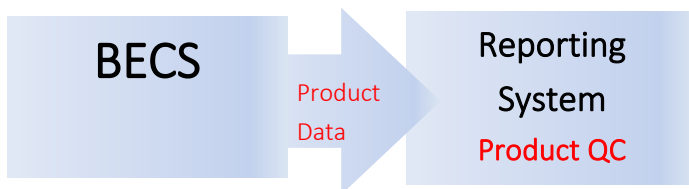
**§880.6310 Medical device data system. – (a) Identification.**

- (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:
  - i. The electronic transfer of medical device data;
  - ii. The electronic storage of medical device data;
  - iii. The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
  - iv. The electronic display of medical device data.
- (2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

However, the current MDDS definition applied too broadly could lead to reclassification of the interfaces for many applications used by blood centers as Class I MDDS devices requiring registration of interfaces and web applications that are designed to allow donors to view donation history, cholesterol results, or blood pressure at the time of a donation. The definition could be interpreted to include any interface or system that is used to report information to donors or to schedule donations because it “augments” the performance of the BECS. Applications that allow donors to schedule appointments online certainly augment the performance of BECS.

**Recommendation**

AABB believes FDA should not classify an electronic transfer of donor eligibility data from a BECS to another software system as a MDDS. Donor blood pressure, heart rate and other data that can be used in making donor eligibility determinations should not be identified as medical device data, even though the BECS uses the same data to make donor eligibility determinations. MDDS related to BECS should explicitly be limited to donor and recipient health, product safety and quality issues.



**Rationale/Supporting Information**

The basis for AABB’s comment is that a MDDS includes an application that transfers donor or product quality data to a general purpose application or an application that converts medical device data from one format to another format in accordance with a preset specification.<sup>iii</sup>

**(3) Neither BECS Accessory nor MDDS**

Simply using data provided by a BECS for other purposes should not result in classification of a system or interface as a BECS accessory or MDDS. Making use of donor eligibility information from the BECS to schedule donor appointments is not the same thing as using data to make additional decisions about donor eligibility. The definition of BECS accessory should clarify that the export of a donor’s eligibility status or other donor data from the BECS to another

application is not a MDDS because neither patient data nor data related to product quality or safety are transferred. The donor's eligibility may be based on data in the BECS, including the donor's blood pressure, heart rate, etc., but export of that information or an application that makes the information available to donors (via internet or telephone) should not be considered a BECS accessory or MDDS. General donor information, even including results of physical screening, should not be included in definition of a MDDS or BECS accessory. While the BECS uses the information to determine donor eligibility, it is not provided to the donor for that purpose.

### **Recommendation**

AABB believes there is an additional "category" that should be considered in clarifying the definition of BECS accessory when the device is neither a BECS/BECS accessory nor a MDDS. AABB recommends the transfer of data (such as donor contact information) that is not related to the intended use for donor eligibility, product safety, product quality or patient safety be excluded from definitions of a BECS Accessory and a MDDS.

### **Rationale/Supporting Information**

With the definitions of BECS Accessory and MDDS applicable only to data transfers that pertain to the intended use to protect the health and safety of patients and donors, FDA's definitions of a BECS accessory and a MDDS should exclude data transfers (regardless of the direction) that do not relate to the intended use of a BECS accessory or MDDS.

The proposed rule appears to exclude an interface between two BECS that does not contain data related to the BECS in its intended use. The proposed rule leads us to interpret the phrase "augment its performance" to relate specifically to the BECS's performance in relation to its intended use. However, BECS often contain data that complements the software's use in making donor eligibility or product determinations. FDA should consider more explicitly excluding systems and interfaces that transfer data to or use data from a BECS if that data is not related to the software's intended use. For example, a program that transfers data related to donors' addresses, phone numbers or other contact information should not be included in the definition of a BECS accessory nor a MDDS, even if the data is being transferred into the BECS. However, some BECS applications use donor addresses to identify duplicate donors. This is another example of data use that should be captured in FDA's explanation of the intent of the requirements.

### **Recommendation**

AABB believes clarification is needed for use of an application relating to donor eligibility dates for various procedure types as calculated in a BECS. The definition and explanation of requirements in FDA's final rule should clarify if the extraction and transmission of a donor's eligibility date for a whole blood procedure to an auxiliary application for managing donor appointments is automatically considered a MDDS.

### **Rationale/Supporting Information**

AABB believes that sending the donor appointment to a BECS, even though the eligibility date was retrieved from the BECS in a separate interface, should be classified as neither BECS Accessory nor MDDS. The table on the following page presents examples of data transfer and use that are consistent with the daily operations in most centers. A system that allows a donor to schedule a donation via the internet or by phone should not be classed as a BECS accessory even though it provides data to a BECS that is used by the BECS to determine eligibility on the selected date.

The types of data and their uses by the BECS need to be more thoroughly examined so that the rules related to BECS Accessory and MDDS can be applied without serious, detrimental impact to the industry.

The table also presents the need for FDA to clarify:

- If FDA bases the classification on how the auxiliary application uses the data.
- If the donor appointment sent to a BECS from an application used for donor scheduling purposes automatically meets the definition of a BECS accessory because it “augments” the BECS performance OR meets the classification of neither BECS nor MDDS.
- If “information can only flow in one direction from the source medical device through the MDDS to the target location – if there is bi-directional information flow, it is no longer a MDDS,”<sup>iv</sup> as stated by FDA representatives, which implies that a two way flow of information is a BECS accessory.
- If the classification of donor appointment management applications using two interfaces are independent routines.

Please refer to the “**Table of Examples to Consider**” on the next page which illustrates some of the concerns about BECS Accessory and MDDS definitions.

**Table of Examples to Consider**

Source	Target	Data Description	Used by target for	Interface Classification
BECS	BECS	Donor Eligibility or Product Quality		<b>BECS Accessory</b>
Donor eligibility information upload	BECS	Blood Loss interval/frequency	Posting Blood Loss in BECS	
BECS	System automating donor eligibility processes	Donor Eligibility	Determining donor eligibility for a procedure	
Any Class II Device (not BECS)	BECS	Donor Eligibility Data, Labeling data, Product Data	Posting the same data in BECS	
<b>MDDS</b>	<b>BECS</b>	<b>Donor or donation data, Labeling data, Product Data</b>	<b>Determine donor eligibility or product Quality</b>	<b>BECS Accessory</b>
Donation Weight Scale	BECS	Weight of Donation	Determine donation volume	
Blood Pressure Monitor	BECS	Donor's blood pressure	Determine donor eligibility	
Hemoglobin measurement device	BECS	Hemoglobin	Determine donor eligibility	
Any Class I Device	BECS	Donor Eligibility Data, Labeling data, Product Data	Posting the same data in BECS	
<b>BECS</b>	<b>General Application</b>	<b>Donor Eligibility or Product Quality</b>		<b>MDDS<sup>v</sup></b>
BECS	State Report for Communicable Diseases	Donor blood test results	State reporting and donor notification processes	<b>MDDS<sup>vi</sup></b>
<b>BECS</b>	<b>Neither BECS Accessory nor MDDS</b>	<b>Neither BECS Accessory nor MDDS</b>		<b>Neither BECS Accessory nor MDDS</b>
BECS	Product QC	Product data	Product Analytics	
BECS	Microsoft Excel	Donor and product data	Business needs and business intelligence	
<i>Continued on next page</i>				



<b>Neither BECS Accessory nor MDDS</b>	<b>BECS</b>	<b>Neither BECS Accessory nor MDDS</b>		<b>Neither BECS Accessory nor MDDS</b>
Product QC	BECS	Product Analytics	Reports in BECS	
Donor Scheduling System	BECS	Donor appointment location, date, time, procedure	Donor Appointments	

Thank you for the opportunity to offer these comments on the proposed rule. We look forward to continuing to work with the FDA on patient and donor safety initiatives. Questions concerning these comments may be directed to [scarayiannis@aabb.org](mailto:scarayiannis@aabb.org).

Sincerely,

Sharon Carayiannis  
Deputy Director, Regulatory Affairs

<sup>i</sup> See *ABC Newsletter*, January 17, 2014, page 3. Darcel Bigelow, a consumer safety officer and leader of the Software Review Team within the FDA's Center for Biologics Evaluation and Review.

<sup>ii</sup> *ibid*.

<sup>iii</sup> *ibid*, page 1, see comments by Richard Chapman, MS, chief of the General Hospital Devices branch in FDA's Center for Devices and Radiological Health

<sup>iv</sup> *ibid*.

<sup>v</sup> This interpretation will require the blood center (or the manufacturer of the application and the interface) to become medical device manufacturer and to list each interface as Class I, MDDS with FDA.

<sup>vi</sup> This interpretation will require the blood center (or the manufacturer of the application and the interface) to become medical device manufacturer and to list each interface as Class I, MDDS with FDA.