

DHQ Changes June 2005 User Brochure Composite

User Brochure Section	Changes	Rationale
Table of Contents	Section identified as "User Brochure" changed to "Flow Charts (Description)"	The section identified as "User Brochure" was rewritten and that header eliminated, but the Table of Contents was not changed at the time of the revision.
Introduction and DHQ Structure and Content	New Sections - Methods of Administration; DHQ Structure and Content; Reformatting Materials	Expanded to organize information and insert additional explanation in response to comments
New Section Methods of Administration	Expanded to include clarification of termination of screening when a deferrable risk is identified early in the screening process	Expanded in response to comments
Page 3; DHQ Structure and Content	Deleted "unabridged" and reworded to read "must not be modified except for local additions"	Unabridged is not the appropriate word to describe the intent
DHQ Structure and Content	Edited to discuss need to renumber questions when a question is deleted or added	Clarify that facilities may use a different numbering system, but should not change the order of the questions
Page 4 2rd bullet	Revised "order and content" to read "order, content, and wording"	Content could be interpreted as subject matter only, and the intent was that the language should not be changed
Page 4 HIV Group O	Deleted question numbers and substituted "The questions related to Africa are recommended...." and "may delete these questions" for "may delete questions 47 and 48"	Eliminate need to rewrite User Brochure if questions are renumbered

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Page 5 examples	Deleted question numbers but provided numbers for examples	Eliminate need to rewrite User Brochure if questions are renumbered
Page 5 Example 3	Inserted the complete question "In the past three years have you been outside the United States or Canada"	Typo - entire question should have been included
Flowcharts	Revised to indicate that flowcharts are not required and may be revised as long as deferrals are not made less strict than FDA and AABB	Clarify that flowcharts are a resource not a strict requirement
Page 8 Glossary: Temporary deferral definition	Changed example to transfusion within the last 12 months	To be complete, the example of tattoo would need to include mention of state regulated entities. A simpler example was substituted to avoid this issue.
References	Added 21 CFR 610.41 and revised AABB Standards to reference the current edition	CFR reference inadvertently omitted; Reference to current edition of AABB Standards eliminates need to change references each time a new edition is published.
References	Deleted May 1 2003 WNV Guidance	Reference no longer needed because question pertaining to WNV symptoms was deleted