

US EPA ARCHIVE DOCUMENT

**Summary of Changes to
AHETF Governing Document: Revised April 7, 2008**

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Comment [J1]: Includes new material summarizing events since June 07

Comment [J2]: Extensively revised

Comment [J3]: Calls for resubmitting GD and SOPs with every study.

Comment [J4]: No longer requires SD to be first-aid certified and trained to recognize HRI. Reduces threshold for stopping rule from 130° to 120° F

Comment [J5]: Allows for use of additional surrogate chemicals not now listed in GD

Comment [J6]: No longer says that some workers might be asked to use equipment with which they were unfamiliar

Comment [J7]: Deleted statement that researcher would be outside private area while dosimeter is removed

¹ Entries highlighted in green have not changed in substance since the draft of June 2007

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Comment [J8]: Changed “detergent” to “surfactant” throughout section 5.5

Comment [J9]: No longer refers to use of unfamiliar equipment. Revised discussion of tank mixes

Comment [J10]: New material about serious accidents

Comment [J11]: Entire section replaced

Comment [J12]: Entire section replaced

Comment [J13]: §11 ¶3 includes new mention of opportunistic collection of MUs for multiple scenarios in a single study. Does not acknowledge requirements for prior approval of all affected scenarios, and for completeness of the sample collection plan in the study protocol.

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Comment [J14]: Extensive editorial revisions

Comment [J15]: Extensive editorial revisions

Comment [J16]: Includes expanded discussion of hand wash methods

Comment [J17]: No longer discusses the meaning of the word “community”

Comment [J18]: No longer refers to (1) use of IRB-approved script and (2) use of video to show dosimetry and how it would be used. Includes new material about opportunities for random selection of workers

Comment [J19]: No longer requires reading ability.

Comment [J20]: No longer permits use of LSC employees as subjects. They are now excluded.

Comment [J21]: Now allows consent interview by other than Study Director. Promises bi-lingual researcher to interview Spanish speaking candidates and minimal use of interpreters.

Comment [J22]: No longer promises to consult with local sources concerning the level of compensation. Now anticipates that IRB might ask for change.

Comment [J23]: Replaces specific references to WIRB with generic refs to IRBs

Comment [J24]: No longer defines “purposive diversity sampling”, “surrogate distribution”, or “target population”. Revised definitions of “benchmark objective”, “cluster”, “distribution of exposure”, “MU”, “normalized exposure”, and “selection”. Added new definitions of “AaiH”, “diversity selection”, “future handler-day population”, “handler-day”, “meta-factor”, “monitoring site”, “potential AI contact”, “reference random sampling model”, “stratified diversity selection”, “two-stage selection of MUs”.

Comment [J25]: Entire Appendix replaced

Comment [J26]: Sections C-1 and C-2 replaced. Remaining sections revised modestly.