Summary of Proposed Revisions to the 2016 Standards
November 2017

The following revisions are proposed to the 2015 ASHI Standards. These revisions went through multiple reviews by the ASHI Board of Directors and Accreditation Review Board as well as a public comment period. The purple changes were previously submitted. The red changes were inadvertently omitted from the first submission. In addition, the appropriate changes requested by CMS were made to standards B.1.1.1 and D.2.5.1 and are listed below in red.

The Table of Contents was changed as follows:

D.5.3.3. Blood, bone marrow and hematopoietic cell transplantation

Abbreviations were added as follows:

The A.2 Abbreviations was changes as follows:

PRA Panel Reactive Antibody

B.1.1.1 The laboratory's CLIA ~~license~~certificate must be conspicuously posted in the clinical laboratory. If applicable, the laboratory's state license must be conspicuously posted. If required for the state where the laboratory is located, the license or current renewal permit of each person performing testing must be conspicuously posted.

D.2.1.2 The laboratory must be in compliance with all applicable federal, state and local laws including but not limited to, laboratory and personnel licensure, those governing laboratory employee health and safety, such as, use of equipment, fire safety, and the storage, handling and disposal of chemical, biological and radioactive materials.

Re: D.2.1.2 - Per OSHA, U.S. laboratories must have access to an updated SDS Manual. Other local requirements are likely to include training programs to review safety requirements for "blood-borne pathogens" including use of personal protective equipment and periodic fire drills with exit routes posted. The laboratory is expected to know what these requirements are. For laboratories in the state of California: Every person or clinical laboratory licensed or registered under this chapter shall report to the California Department of Public Health, Laboratory Field Services within 30 days of change of name or address.

D.2.5.1 Laboratories must have a written agreement for histocompatibility testing with each transplant program or OPO they serve. Laboratories must review each agreement ~~bi-annually~~ biennially and revise as necessary.

Re: D.2.5.1 These must be agreements relating to each type of transplant program, including HPC transplant programs. Only the laboratory is required to review the agreement ~~bi-annually~~ biennially unless substantial changes are made that require the program's review and approval.

RE: D.2.6.1.1 - Competency assessments must be performed on individuals serving as clinical consultants, technical supervisors and/or general supervisors based on their regulatory responsibilities including specific responsibilities designated to them. Competency assessment does not need to be performed for laboratory directors unless they perform patient testing. Additionally, if the laboratory director fulfills additional roles such as technical supervisor, clinical consultant, and/or general supervisor, no competency assessment is required for these roles unless they perform patient testing. Please note that competency assessment is required for the roles of Technical Supervisor, Clinical Consultant, and General Supervisor when someone other than the laboratory director fills these positons.

Re: D.2.6.2 All 6 elements of competency must be assessed for all staff who perform testing on patient specimens. Documentation must include direct observations of every test category (HLA typing, antibody identification, crossmatch etc.) for which ~~a technologist is~~ testing staff are responsible. This observation must include the performance and maintenance of instruments used in performing these tests. In addition, the ability to recognize and solve problems must be documented (for example providing written answers to a problem scenario or documentation of an actual situation).

Re: D.4.1.5.3 -This ~~S~~standard also applies to tests not specifically covered by ASHI Standards if such testing is performed in relation to transplantation and immunogenetics testing (e.g., testing for polymorphisms of MICA, cytokine genes, or using Next Generation Sequencing test methods). Note that if results are reported to a USA physician with patient identifiers and may, therefore, be used by the physician in making clinical decisions, these are, per CMS, not “research” tests.

Re: D.5.2.2.24 - Independent review is defined as validated software analysis or review by a qualified individual of the software output. The data output results must be reviewed by a qualified individual before release. Automated analysis by validated software alone is sufficient for ~~stem~~ hematopoietic cell donor registry testing only.

~~**Re: D.5.2.10.1** - Note that since the Cylex® test is FDA approved and does not require an aseptic work area (incubations are less than 18 hours) this standard has been made less stringent. Also note that it is OK that lymphocyte viability is not checked in this assay.~~

~~**Re: D.5.2.10.2** - ASHI will also accredit laboratories doing other relevant cellular tests such as primed lymphocyte typing or limiting dilution assays for cytotoxic T-cell precursors for Hematopoietic Cell donor selection.~~

D.5.3.3 Blood, Bone Marrow and Hematopoietic ~~Stem~~ Cell Transplantation (H~~S~~CT)

D.5.3.3.1 Laboratories performing testing for blood, bone marrow and hematopoietic cell transplantation must:

D.5.3.3.1.3 Repeat HLA typing of a related or unrelated ~~stem~~ hematopoietic cell donor using a new sample such that the individual's HLA typing is verified prior to ~~stem~~ hematopoietic cell collection.

Re: D.5.3.8.1 This agreement may be included in the existing agreement with the transplant program or as a separate document. The UNOS match system does not fulfill the requirement for performing a pre-transplant final crossmatch.

D.6.2.2.3 The Laboratory / Institution's name, director’s name, address and CLIA number or ASHI accreditation number for laboratories not subject to CLIA.

Re: D.6.2.2.3 – If required by the state where the laboratory is located, the director’s name on the report should be the director listed on the CLIA certificate.

Re: D.6.2.2.11 – The WHO recognized serological specificities can be found in the last published HLA Dictionary. Additional information can be found at ~~http://www.ebi.ac.uk/ipd/.~~ http://hla.alleles.org/nomenclature/index.html.

D.6.2.2.11 All phenotype terminology using ~~relevant internationally~~ WHO approved nomenclature.