**Section 661.15 Definitions**

"Act" means the Newborn Metabolic Screening Act [410 ILCS 240].

"Advisory Committee" means the Genetic and Metabolic Diseases Advisory Committee appointed by the Director.

"Clinical and Laboratory Standards Institute" or "CLSI" means a global nonprofit standards-developing organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community.

"Clinical Laboratory Improvement Amendments" or "CLIA" means federal regulations (Centers for Medicare and Medicaid Services, United States Department of Health and Human Services) providing standards applicable to all facilities or sites in the United States that test human specimens for health assessment or to diagnose, prevent or treat disease.

"Department" or "DPH" means the Department of Public Health.

"Director" means the Director of the Department of Public Health.

"Formula" means a medically prescribed treatment substance that has been designed to treat a specific metabolic disorder.

"Lysosomal storage disorders" or "LSD" means disorders including, but not limited to, the following: Krabbe, Pompe, Gaucher, Fabry, Niemann-Pick and Mucopolysaccharidosis Type I (Hurlers syndrome) and Mucopolysaccharidosis Type II (Hunters syndrome), which are inherited metabolic disorders caused by lysosomal dysfunction, usually as a consequence of deficiency of a single enzyme required for the metabolism of lipids, glycoproteins or mucopolysaccharides.

"Newborn screening" or "testing" means the testing of a blood sample for classical phenylketonuria (PKU) and certain other amino acid, organic acid, and fatty acid oxidation disorders, primary hypothyroidism, classical galactosemia, congenital adrenal hyperplasia due to 21-hydroxylase deficiency, biotinidase deficiency, sickle cell disease/trait, cystic fibrosis, lysosomal storage disorders, and severe combined immunodeficiency. At times, variant forms of some disorders, or related conditions, may also be identified.

"Quality control" means a procedure or set of procedures to assure the accuracy of results reported by the laboratory.

"Tandem mass spectrometry" or "MS/MS" means use of a tandem mass spectrometer and associated software to test a newborn screening sample.

"Severe combined immunodeficiency and T cell lymphopenia or "SCID" means a primary immune deficiency characterized by a severe defect in both the T and B lymphocyte systems.

"Supplemental test" means any test approved by the United States Food and Drug Administration or validated under a laboratory's CLIA certification that is used to further characterize a newborn screening specimen that had received a positive (i.e., abnormal) result when initially screened by the laboratory.

"Using accepted statistical techniques" means using techniques that have been published in peer reviewed scientific literature.

(Source: Amended at 38 Ill. Reg. 12509, effective June 2, 2014)