



Quality Division Use Only

Scientific Area Committee (SAC): Subcommittee:

Standard/Guidelines Title

Date added to OSAC Registry

Can the Standard/Guidelines be followed in totality?

Please explain if the Standard/Guidelines and the applicable clauses that cannot be followed in their totality:

Clause 5.3.2., "For materials without an acceptable certificate of analysis, the laboratory shall characterize the target compound by a minimum of two structural elucidation techniques." The Toxicology section uses one reference material, 1,1-difluoroethane (DFE), that cannot be purchased as a certified reference material in the appropriate solvent. The currently available certified reference material is in methanol, which interferes with identification of DFE by the current HFSC volatiles analysis using headspace GC-FID. The Toxicology section uses a commercially available product, Dust-Off® as their reference material for both the cutoff calibrator and positive control. HFSC only has one available analytical technique (GC-MS) capable of providing structural elucidation data for DFE in Dust-off®.

Clause 5.4., "When provided, the manufacturer's recommended storage conditions for reference material shall be followed." Toxicology utilizes reference materials from different manufacturers/vendors. Manufacturers may list different storage conditions for the same materials in the same solvents. Storing the same reference material in different conditions and in different physical locations would be burdensome and inefficient. In these situations, HFSC will utilize the storage conditions they deem appropriate to their method, based on validations studies and storage of similar compounds.

Compliance plan to achieve conformance to Standard/Guidelines:

Clause 5.3.2: HFSC will purchase and utilize certified reference material in the appropriate solvent for DFE if one becomes commercially available. Alternatively, once HFSC acquires a headspace GC-MS system and moves the DFE method, the existing certified reference material can be used.

Clause 5.4: In communication with the Toxicology OSAC subcommittee, further clarification to the clause was provided. Consensus from the subcommittee executive group is that compliance with this standard can be achieved when storing Certified Reference Materials (CRM) at a different temperature than manufacture's recommendations as long as the justification for doing so is documented, and it can be demonstrated that the temperature selected has no effect on CRM stability. The Toxicology section has validation studies to support the storage conditions used. As a result, HFSC is meeting the intent of this clause.

The Toxicology section incorporated all other applicable clauses in the Toxicology Analytical Manual v4.0, issued on March 4, 2024.



Declaration of Compliance to OSAC Registry Standard/Guidelines:

As of April 23, 2024, the Toxicology section is compliant with all other requirements listed in the Standard for a Quality Control Program in Forensic Toxicology Laboratories.

Technical Leader: N/A

Date: N/A

Section Manager/

Designee: *Cassandra Duvall*
Cassandra Duvall (Jul 2, 2024 16:03 CDT)

Date: Jul 2, 2024

Division Director: *Amy Castillo*

Date: Jul 8, 2024

Quality Director: *Jackie Moral*

Date: Jul 11, 2024