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Harmonization of NIOSH Sampling and Analytical Methods with Related International Voluntary Consensus Standards

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INTRODUCTION

The *NIOSH Manual of Analytical Methods* (NMAM®) is a compilation of analytical methods for air, biological, surface (including dermal) and bulk samples, as well as biological specimens, that have been evaluated and validated in consideration of their fitness for purpose for workplace exposure monitoring. NIOSH sampling and analytical methods are intended to promote accuracy, sensitivity, and specificity in industrial hygiene analyses and related applications. NMAM is published online and is available worldwide free of charge.[1] Presently in its 5th edition, NMAM is constantly updated as new methods are developed and validated and as revised methods are re-evaluated and their performance verified. Often there are situations during use where certain NIOSH methods may require modification, for example, to accommodate interfering compounds from a particular workplace, to take advantage of unique laboratory capabilities, to make use of equivalent sample preparation or analysis techniques, or to make possible the analysis of a single sample for multiple contaminants. NIOSH methods are evaluated with respect to the NIOSH accuracy criterion $A = \pm 25\%$, wherein at least 95% of measurements must fall within 25% of the true (or reference) value.[2] When method modifications are made, quality control data demonstrating the reliability of the modified method must be obtained, recorded and reported. The methods published in NMAM are relied upon by authoritative bodies such as accrediting organizations and regulatory agencies. Besides sampling and analytical methods, NMAM also includes chapters on quality assurance, portable instrumentation, analysis of fibers, aerosol sampler design, and other guidance on specific areas of interest.

To address requirements for harmonized methods for use by occupational hygiene laboratories, international voluntary consensus standard test methods have been developed and promulgated by ASTM International,[3] the Comité Européen de Normalisation[4] (European Committee for Standardization, CEN) and the International Organization for Standardization[5] (ISO). Like NIOSH methods, these consensus standard procedures describe aspects of sampling and sample preparation as well as measurement, although normally in exhaustive, specific detail. Other related consensus standards offer thorough guidance on sample collection, sample preparation and analytical protocols. Harmonization of NIOSH methods with related voluntary consensus standards is a strategic goal for the 5th edition of NMAM.

Current efforts to update NMAM may also include validated methodologies developed by sister organizations both nationally and internationally, such as the US Occupational Safety and Health Administration (OSHA), the Health and Safety Laboratory (HSL) in the United Kingdom, the Institut National de Recherche et de Securité (National Institute of Research on Health and Safety at Work, INRS) in France and the the Institut für Arbeitsschutz der Deutschen Geseltzlichen Unfallversicherung (Institute for Occupational Safety and Health of the German Social Accident Insurances, IFA) in Germany. NIOSH is keeping abreast of new industrial hygiene and biomonitoring methods and consensus standards developed globally. NIOSH researchers coordinate and collaborate externally and often consider suitable validated methods developed by other institutes and organizations, domestic as well as international.

HARMONIZATION OF ANALYTICAL METHODS

In accordance with and observance of the National Technology Transfer and Advancement Act (NTTAA),[6] a main goal of ongoing NIOSH methods development activities is to ensure that NIOSH methods are harmonized with relevant international voluntary consensus standards. The NTTAA directs US federal government agencies to: (1) rely on applicable voluntary consensus standards in lieu of procedures and documents developed in-house; and (2) participate in the development of pertinent consensus standards that are related to the agencies' activities. In the course of sampling and analytical methods development, NIOSH may consider adapting applicable existing standards promulgated by ISO, CEN and/or ASTM International.

Regarding method evaluation and validation, an important standard published by CEN, i.e., EN 482, outlines the general requirements for measurement of chemical agents in workplace air.[7] This European standard specifies an upper limit for expanded uncertainty *U* of ±30% for an acceptable sampling and analytical method when applied to measurements spanning the OEL (i.e., between 0.5 – 2× the OEL). EN 482 also cites an upper limit for *U* of ±50% for measurement of analyte levels between the method quantitation limit and ½ of the applicable OEL. It is pointed out that for most applications, expanded uncertainty (for coverage factor *k* of 2-3) is equivalent to accuracy as defined by NIOSH.[8,9] NIOSH[2] and CEN[7] method evaluation protocols account for all potential sources of experimental error (both random and systematic), in accordance with the ISO guidelines on measurement uncertainty.[10] For a given measurement method, the final estimate of accuracy or expanded uncertainty is a result of combined contributions from propagated errors occurring throughout the sampling and analytical process.

Of the more than 300 published NIOSH sampling and analytical methods,[1] a large number have related or parallel international voluntary consensus standards that have been produced by ASTM International,[3] ISO[4] and/or CEN[5] (Table I). In many instances the consensus standard procedures listed were developed with a basis on NIOSH methods, while in some cases NIOSH methods are themselves based on more recently developed ASTM and/or ISO standards. Ideally sampling and analytical methods for toxic agents in workplaces are performance-based, and harmonizing NIOSH methods with consensus standards is not necessarily as important as ensuring that the methods are adequately validated, sufficiently accurate and fit for purpose. NIOSH scientists have participated in the development of related consensus standards for many years. This helps to ensure that NIOSH methods are harmonized with applicable consensus standards and also fosters cooperation and collaboration between NIOSH experts and fellow scientists from domestic organizations and sister institutes in countries around the world.

As a related resource, the IFA in Germany, in cooperation with experts from other member European nations participating in deliberations of CEN Technical Committee (TC) 137,[5] has made available a database of over 225 validated sampling and analytical methods for more than 125 substances.[11] Ratings of methods for these analytes are provided based on factors established by a European expert committee.[12] Presently within CEN there is an ongoing project to update and expand this very useful methods database. Many NIOSH methods and international consensus standards can be found cited in this database.

Various older NIOSH methods for organics listed in Table I, such as those for organic gases and vapors, are based on the use of packed gas chromatography (GC) columns. In practice, packed GC columns are rarely used now and have been largely replaced by capillary GC columns. The use of capillary GC columns has been described in many of the more recently published consensus standards (ASTM International and ISO) listed in Table I. In order to modernize many of these older NIOSH methods (which were developed mostly in the 1970s and 1980s), there is a concerted effort to update a number of the NIOSH GC analytical methodologies for organic vapors and gases. Thus a project is now underway to validate a multi-analyte procedure (or procedures) that can be used to measure multiple gaseous organic compounds in occupational atmospheres by means of sorbent sampling and capillary GC separation / isolation, followed by appropriate detection schemes like flame ionization detection (FID), photoionization detection (PID) or mass spectrometry (MS). This will result in the promulgation of new NIOSH methods for toxic organic gases and vapors that are up to date and better harmonized with applicable international consensus standards.

GUIDANCE DOCUMENTS

Within NMAM, separate from the sampling and analytical methods, are eighteen chapters covering a variety of subjects.[1] Explanatory chapters on quality assurance, sampling guidance, portable instrumentation, method development and evaluation, aerosol collection, measurement of specific analytes or groups of analytes, etc., provide valuable guidance to the users of NIOSH methods. These chapters provide a convenient resource that augments related consensus standards and technical information often available elsewhere in monographs and texts. Presently, efforts are underway to update several chapters that have not been revised in a number of years. Also, new chapters on key subjects including guidelines for the performance of biomonitoring methods and direct-reading instruments are planned. Similarly for sampling and analytical methods, harmonization of the guidelines put down in these chapters with relevant consensus standards guidance is essential and will be ensured.

Many of the methods published in NMAM specify the collection of workplace aerosol samples using filter samplers such as 37-mm closed-face filter cassettes (CFCs). NIOSH considers that all particles entering the sampler (e.g., CFC) should be included as part of the sample whether they deposit on the filter or on the inside surfaces of the sampler.[13] All aerosol particles entering occupational air samplers should be included in the sample for gravimetric analysis as well as for analytes such as metals and metalloids. Hence, during sample preparation and analysis, procedures should be used to account for material adhering to the internal walls of sampling cassettes. In the spirit of harmonization, consideration of internal sampler wall deposits is included in related international voluntary consensus standards that describe the sampling and analysis of airborne metals and metalloids.[14,15]

Also linked to guidance on NMAM sampling and analytical procedures for gases and vapors are relevant ASTM International and ISO standards describing the evaluation of diffusive samplers.[16,17] Although validation of passive monitors[18] may be expensive (sometimes prohibitively so), the ability to obtain good estimates of analytical uncertainty for diffusive sampling techniques is important for achieving more accurate real-time exposure assessments. This is especially true of screening techniques, which typically require vast amounts of performance data to enable adequate characterization of overall measurement uncertainty (and consequent evaluation of fitness-for-purpose).[19] Harmonized guidance on diffusive sampling[16,17] should prove beneficial for evaluating newer passive monitoring techniques such as canister sampling, helium-diffusive sampling and solid-phase micro-extraction.

Increased use of direct-reading monitors for occupational hygiene applications[20] underscores the need for standardized evaluation and validation protocols for these devices. Recently, guidance on evaluation of direct-reading instruments for gas and vapor monitoring has become available from NIOSH,[21] for example with applications to four-gas monitors. Currently there are efforts to develop international voluntary consensus standards for real-time monitoring devices that will accommodate not only onsite quantitative analysis but also screening techniques for myriad applications.

CONCLUDING REMARKS

Further efforts are currently underway that will fulfill requirements for fully validated NIOSH and consensus standard procedures for workplace exposure measurements. For example, new procedures describing the analysis of all aerosol particles entering a given air sampling device are being developed and evaluated. Through effective use of national and international collaborations and resources, further advances in the field of industrial hygiene chemistry are underway and improvements in sampling and analytical protocols are continually being explored. The *NIOSH Manual of Analytical Methods* remains an invaluable global resource for the occupational hygiene profession. Harmonization with voluntary consensus standards organizations such as ASTM International, CEN and ISO is crucial in leveraging current and future applied research, as well as technology transfer endeavors, within the discipline of occupational hygiene sampling and analysis.

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TABLE I

NIOSH Sampling and Analytical Methods and Related / Parallel International Voluntary Consensus Standards

NIOSH Method(s) [1]	*ASTM Standard(s)* [3]	*ISO Standard(S)* [4]	*CEN (EN) Standard(s)* [5]
0500 & 0501, Particles not otherwise regulated, total (gravimetric) 5000 & 5100, Carbon black (gravimetric)	D6552, Controlling and characterizing errors in weighing collected aerosols	15767, Controlling and characterizing uncertainty in weighing collected aerosols	—
0600, Particles not otherwise regulated, respirable (gravimetric)	D4532, Respirable dust in workplace atmospheres D6552, Controlling errors in weighing collected aerosols	15767, Controlling and characterizing uncertainty in weighing collected aerosols	—
0800, Bioaerosols (by pumped sampling) 0900, Mycobacterium tuberculosis (filter sampling)	—	13137, Pumps for sampling chemical & biological agents	13098, Guidelines for measuring microorganisms & endotoxin 13137, Pumps for sampling chemical & biological agents 14583, Bioaerosol sampling – requirements & methods
1003, Halogenated hydrocarbons, by sorbent tube & gas chromatography (GC) 1022, Trichloroethylene by sorbent tube & GC	D3686, Sampling organic vapors by charcoal tube D3687, Analysis of organic vapors collected by charcoal tube	9486, Vaporous chlorinated hydrocarbons by charcoal tube / solvent desorption / GC	1076, Gases and vapor measurement by pumped sampling – requirements & test methods
1007, Vinyl chloride by charcoal tube & GC	D4766, Vinyl chloride by charcoal tube	—	—
1008-1460, Organic vapors (various) by charcoal tube & GC	D3686, Sampling organic vapors by charcoal tube D3687, Analysis of organic vapors collected by charcoal tube	16017-1, Organic vapors by charcoal tube & GC	1076, Gases and vapor measurement by pumped sampling – requirements & test methods
1500, Hydrocarbons, BP 36-126 °C, by charcoal tube & GC 1501, Aromatic hydrocarbons by charcoal tube & GC	D3686, Sampling organic vapors by charcoal tube D3687, Analysis of organic vapors collected by charcoal tube	16017-1, Organic vapors by charcoal tube & GC 9487, Vaporous aromatic hydrocarbons by charcoal tube / solvent desorption / GC	1076, Gases and vapor measurement by pumped sampling – requirements & test methods
1614, Ethylene oxide by charcoal tube & GC	D4413, Ethylene oxide, charcoal tube sampling D5578, Ethylene oxide, derivatization technique	—	—
2001, Aromatic amines by sorbent tube & GC 2010, Aliphatic amines by sorbent tube & GC	D3686, Sampling organic vapors by charcoal tube D3687, Analysis of organic vapors collected by charcoal tube	—	—
2018, Aliphatic aldehydes by derivatized silica cartridge & liquid chromatography (LC)	D5197, Formaldehyde and other carbonyls by derivatized silica cartridge & LC	—	

NIOSH Method(s) [1]	*ASTM Standard(s)* [3]	*ISO Standard(S)* [4]	*CEN (EN) Standard(s)* [5]
2539, Aldehydes, screening, by GC / GC GC-mass spectrometry (MS)			
2549, Volatile organic compounds (VOCs) by sorbent tube / thermal desorption / GC-MS	—	16200-1, VOCs by solvent desorption / GC	—
3600 & 3601, Maneb by dermal patch & hand wash (respectively)	—	TR 14294, Measurement of dermal exposure	TS 15278, Evaluation strategy for dermal exposure TR 15279, Measurement of dermal exposure
3700, Benzene by portable GC	—	—	4554-1, -2, -3 & -4, Direct measurement of toxic gases and vapours
3800, Inorganic and organic gases by extractive Fourier transform infrared (FTIR) spectrometry	E1982, Gases and vapors by open-path FTIR spectrometry	—	4554-1, -2, -3 & -4, Direct measurement of toxic gases and vapours
5040, Elemental carbon (diesel particles) by thermo-optical analysis	D6877, Diesel particulate exhaust by thermo-optical analysis	—	14530, Diesel particulate matter – general requirements
5042, Benzene-soluble particulate matter	D4600, Benzene-soluble particulate matter D6494, Asphalt fume in benzene-soluble fraction	—	—
5503, Polychlorobiphenyls by filter + sorbent & GC	D4861, Pesticides and polychlorinated biphenyls – guidance on sampling and analytical methods	—	—
5521, Monomeric isocyanates by impinger sampling & LC 5522, Isocyanates by impinger sampling & LC 5525, Isocyanates, total, by filter or impinger sampling & LC	D5836 & 5932, Toluene diisocyanates (TDI) by LC D6561, Hexamethylene diisocyanate (HDI) aerosol by LC D6562, Gaseous HDI by LC	11734-1, Isocyanates by LC-MS; 11734-2, Amines & aminoisocyanates by LC-MS 11735, Total isocyanates by LC 11736, Isocyanate by double-filter sampling & LC 16702, Total organic isocyanates by LC 17737, Guidelines for selecting isocyanate methods	—
5524, Metalworking fluids – gravimetric analysis	D7049, Metal removal fluid aerosol	—	
5506, Polynuclear aromatic hydrocarbons by filter + sorbent & LC 5515, Polynuclear aromatic hydrocarbons by filter + sorbent & GC 5800 Polycyclic aromatic compounds by filter + sorbent & flow-injection analysis	D6209, Polycyclic aromatic compounds by sorbent-backed filter & GC-MS	—	—
5600, Organophosphorus pesticides by filter +	D4861, Pesticides and polychlorinated biphenyls	—	—

NIOSH Method(s) [1]	*ASTM Standard(s)* [3]	*ISO Standard(S)* [4]	*CEN (EN) Standard(s)* [5]
sorbent & GC 5601, Organonitrogen pesticides by filter + sorbent & LC			
6004, SO_2 by treated filter & IC	D2914, SO_2 by bubbler & colorimetry	—	
6009, Hg by sorbent tube & cold vapor atomic absorption (CVAA)	—	17733, Hg by CVAA or cold vapor atomic fluorescence	—
6013, H_2S by charcoal tube and ion chromatography (IC)	4913, H_2S by length of stain reading	—	—
6014, NO & NO_2 by sorbent tube & visible absorption spectrophotometry 6700, NO_2 by diffusive sampler & visible absorption spectrophotometry	—	8761, NO2 by detector tube & direct indication	—
6604, CO by electrochemical sensor	—	8760, CO by detector tube	4554-1, -2, -3 & -4, Direct measurement of toxic gases and vapours
7013, Al; 7020, Ca; 7024, Cr; 7027, Co; 7029, Cu; 7030, Zn; 7048, Cd; 7074, W (insoluble); 7082, Pb, by flame atomic absorption spectrometry (FAAS)	D4185, Metals by FAAS D6785, Pb by FAAS or graphite furnace atomic absorption spectrometry (GFAAS)	8518, Pb by FAAS or electrothermal atomic absorption (ETAAS) 11174, Cd by FAAS or ETAAS	13890, Metals & metalloids – requirements & test methods
7056, Ba, soluble compounds; 7074, W (solubles), by FAAS	—	15202-2, Annex B: Soluble metals and metalloids in workplace air	13890, Metals & metalloids – requirements & test methods
7105, Pb by GFAAS	D6785, Pb by FAAS or GFAAS	8518, Pb by FAAS or ETAAS	13890, Metals & metalloids – requirements & test methods
7300, 7301, 7302, 7303, 7304 Elements by ICP-AES	D7035, Metals and metalloids by ICP-AES	15202-1, -2 & -3, Metals and metalloids by ICP-AES (sampling, preparation and analysis)	13890, Metals & metalloids – requirements & test methods
7400, Asbestos fibers by phase-contrast microscopy (PCM) 7402, Asbestos fibers by transmission electron microscopy (TEM)	D7200, Airborne fibers in mines & quarries, including asbestos, by PCM & TEM D7201, Asbestos fibers by PCM with TEM option	8672, Airborne inorganic fibres by PCM	—
7401, Alkaline dusts, by acid-base titration	—	17091, LiOH, NaOH, KOH & $CaOH_2$ by suppressed IC	—
7500, Respirable crystalline silica (RCS) by X-ray diffraction (XRD) 7602, RCS by infrared (IR) 7603, RCS in coal mine dust	—	24095, Guidance for measuring respirable crystalline silica	—
7600 & 7703, Cr(VI) by	D6832, Cr(VI) by IC	16740, Cr(VI) by IC	—

NIOSH Method(s) [1]	***ASTM Standard(s)*** [3]	***ISO Standard(S)*** [4]	***CEN (EN) Standard(s)*** [5]
Ultraviolet-Visible (UV-Vis) spectrophotometry 7605, Cr(VI) by IC and UV-Vis detection	and UV-Vis detection	and UV-Vis detection	
7704, Be in air by fluorescence 9110, Be in wipes by fluorescence	D7202, Be in air or wipes by fluorescence D7296, Be in dry wipes D7707, Be wipe specification	—	—
7910, Arsenic trioxide by GFAAS	—	11041, Arsenic and arsenic trioxide by atomic absorption	—
7902, Fluorides, aerosol & gas, by ion-selective electrode (ISE)	D4765, Fluorides by ISE	—	—
7906, Fluorides, aerosol & gas, by IC	—	21438-3, Fluorides, aerosol & gas, by IC	—
7907, HCl, HBr & HNO_3 by IC	D7773, HCl, HBr & HNO_3 by suppressed IC	21438-2, HCl, HBr & HNO_3, by IC	—
7908, H_2SO_4 & H_3PO_4 by IC	D4856, H_2SO_4 by IC	21438-1, H_2SO_4 & H_3PO_4 by IC	—
9100 & 9105, Pb on wipes 9102, Elements on wipes	D6966, Wipe sampling for metals D7659, Guide for elemental surface sampling D7822, Dermal wipe sampling for elemental analysis E7192, Pb wipe specification	TR 14294, Measurement of dermal exposure	TS 15278, Evaluation strategy for dermal exposure TR 15279, Measurement of dermal exposure
9200 & 9201, Chlorinated and organonitrogen herbicides, hand wash & dermal patch (respectively) 9202 & 9205, Captan and thiophanate-methyl in hand rinse and dermal patch (respectively)	—	TR 14294, Measurement of dermal exposure	TS 15278, Evaluation strategy for dermal exposure TR 15279, Measurement of dermal exposure