

USEPA Office of Solid Waste and Emergency Response/Office of Resource Conservation and Recovery Policy on the Use of “Test Methods for Evaluating Solid Waste, Physical/Chemical Methods” (SW-846)

The United States Environmental Protection Agency’s (EPA) Office of Resource Conservation and Recovery (ORCR) provides analytical and sampling methods to assist the regulated and regulatory community and others in implementing the Resource Conservation and Recovery Act (RCRA). These methods are published in the Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846) and are available on the ORCR Web site (www.epa.gov/epawaste/hazard/testmethods/index.htm). With the exception of those particular methods which are promulgated in the regulations to implement RCRA (see 40 CFR 260.11), the remaining methods are considered guidance, and users may select any scientifically appropriate method when conducting analyses to comply with the RCRA regulatory program.

The Methods Innovation Rule (MIR) published on June 14, 2005 (70 FR34538), reemphasized the flexible approach in method selection, when appropriate, when testing for compliance, under RCRA. Since the publication of this rule, ORCR no longer uses a formal rulemaking process for publication of method updates to SW-846. EPA informs the regulated and regulatory community of new methods and updates to SW-846 and solicits comments on them through a Notice of Availability published in the Federal Register. This approach is consistent with ORCR’s commitment to fully implement the Agency’s performance-based measurement system (PBMS) approach to regulation.

A new effort was developed and approved to reinvigorate the goals of PBMS with the versatility of each of our program’s needs. It is called the Flexible Approaches to Environmental Measurements—The Evolution of the Performance Approach which the Science and Technology Policy Council (STPC) approved on February 15, 2008. In 2009, ORCR subsequently adopted the new “Performance Approach” as defined by the Forum on Environmental Measurements (FEM). The FEM is a standing committee of senior EPA Environmental Protection managers established to develop policies to guide the Agency’s measurement community in: validating and disseminating methods for sample collection and analysis; for ensuring that monitoring studies are scientifically rigorous, statistically sound, and yield representative measurements; and for employing a quality systems approach that ensures that the data gathered and used by the Agency are of known and documented quality.

After shortening the name of the PBMS effort to the “Performance Approach,” the FEM’s Performance Approach Action Team took a look at the issues surrounding the lack of the program’s progress with the ultimate conclusion that the “one size fits all” approach does not work for the diversely different programs and authorities each of our major program offices (i.e., air, pesticides, waste, and water) has in carrying out their work. To avoid the proliferation of terminology, ORCR has adopted the “Flexible Approach” which is consistent with ORCR’s approach to environmental management, based on the goals and statutes of EPA program offices.

Under the PBMS approach for RCRA, when labs conducted regulatory required monitoring, the regulated community had to either employ a scientifically appropriate method published in SW-846 or use any other scientifically appropriate method from another reliable source. This is still true under the Flexible Approach. However, when choosing a reliable alternative source, the focus should be on measurement objectives, rather than on measurement technologies. In all cases, the user must demonstrate the method selected generates data that are appropriate for the intended use. Although both approaches are applicable for RCRA, ORCR had dropped the term PBMS, and strongly supports

the use of the new Flexible Approach to be consistent with the Agency's new guidance that allows each program to determine program specific flexibility when addressing waste analysis issues.

ORCR strongly recommends that persons use the latest version of a SW-846 method whenever possible, especially in new monitoring situations, since updated versions of the methods EPA publishes generally are in the Agency's view less subject to misinterpretation, yield improved precision and/or bias, or provide for the use of newer and, often, more cost-effective technologies. In situations where it may not be appropriate to use the latest method in SW-846, earlier versions may be used. These situations may include, but are not limited to, those where an earlier version of a method is required for existing permits, consent decrees, waste analysis plans or sampling analysis plans. In addition, laboratories, especially small laboratories, may find a previous version of a SW-846 method appropriate if it is more cost-effective in meeting the project-specific objectives. The Agency is not imposing restrictions on the use of earlier versions of non-required methods contained in SW-846 or precluding the use of previous guidance. Nonetheless, the adoption of the latest method version is recommended and should be accomplished as soon as possible, as appropriate. When methods are employed, it is the responsibility of the user to ensure that the method yields data of a quality appropriate for the particular application for which it is being used.

EPA views the methods in the SW-846 compendium as tools for the user to employ in developing individual standard operating procedures to meet the goals and objectives of specific projects. This approach enables the user to optimize and modify methods for effective performance on unique projects. The SW-846 methods are for most applications considered as guidance with the exception of those methods required by the RCRA regulations (i.e., Method-Defined Parameters (MDPs), see 40 CFR 260.11).

In situations where the user is not certain whether the selected method or method modification is appropriate, EPA recommends regulated entities contact and seek approval as needed from the appropriate regulatory agency (e.g., Federal or State/local government) before applying any method on a specific project, including situations where the method is used verbatim.

EPA may publish new methods, revise existing methods, or withdraw methods from the SW-846 compendium whenever it deems it appropriate. For example, methods may be updated in order to reflect new advancements in technology, to reflect the addition of new performance data, or to clarify areas of the procedure that experience indicates may be misunderstood. Methods may also be revised to reflect new EPA policy regarding the use of certain chemicals and reagents. In other cases, methods are removed if the technology is no longer available or applicable. ORCR has developed specific procedures for releasing updates, revisions, or withdrawing methods, which are designed to minimize disruption to regulatory processes. Specific definitions for the terms associated with a method's status, which support the change procedures, have been developed and provided below.

The Agency will only post the most recent version of a final SW-846 method on the ORCR Web page as part of the SW-846 methods compendium (www.epa.gov/epawaste/hazard/testmethods/index.htm). Prior versions of methods formerly contained in SW-846 and still considered appropriate for use will be available through a separate hyperlink in the future. EPA's objective is to identify and make available on the Agency's SW-846 Web site the latest information regarding the methodologies that generate effective data at minimum costs in response to new technological or scientific advancements, while, at the same time, making available earlier versions for those situations where such methods may be

needed or appropriate (e.g., to determine how a particular analysis had been performed, to determine how to comply with a specific permit requirement, etc.).

SW-846 Methods Status Definitions

Analytical methods are officially made a part of the SW-846 manual through a rigorous process of technical evaluation both within the Agency and through external review. Methods are also revised as needed after a formal evaluation process by analytical experts (e.g., SW-846 work and focus groups) and an announcement of method availability and request for public comment in the Federal Register as a Notice of Availability. During the method development/evaluation process, the methods go through various stages of review and revision. The methods are officially included as part of an update to the most current edition of SW-846 at the conclusion of this process.

ORCR employs a specific naming convention (i.e., method number and letter suffix) when publishing methods. The naming convention is intended to minimize confusion within the user community regarding a method's developmental status. The method number designates the underlying technology (e.g., 8000 series methods designate determinative procedures for organic compounds). A revision to a method where the underlying technology does not change is indicated by continued use of the same method number and letter, but with a new issuance date. If the revision retains the underlying technology, but does not affect the precision and/or accuracy of the data, the revision is considered to be minor or nonsignificant and the method number and letter is not changed or sequenced.

If, on the other hand, the revision retains the underlying technology, but changes the precision and/or accuracy of the data, the change is considered to be significant and is indicated by a subsequent letter suffix (e.g., changes from 8270C to 8270D) and a new issuance date. For example, if the quality control recommendations are changed in a manner that improves the bias or precision of the method, but does not change the underlying technology (e.g., a tightening of the calibration acceptance criteria), the method number stays the same, but the letter suffix is sequenced to the next letter. The differences between the earlier and later versions of a method are detailed in the method summary section of the revised version regardless of the type of change.

Examples of changes that may be considered minor or nonsignificant include, but are not limited to: Language added to a method to provide increased clarity or guidance; expansion of lists of acceptable instrumentation, applicability of the method to a matrix not previously referenced, adding new compounds to the list of applicable compounds, or changes to instrument specifications which do not result in an existing acceptable instrument being rendered unacceptable; or formatting and editorial changes that are designed to improve readability or correct spelling or grammatical errors.

ORCR has defined a "significant change" as a change that results in improved analytical results (e.g., changes that result in reducing analytical bias or improving data precision). Examples of significant changes may include, but are not limited to: a change in the operating parameter which reduces analytical flexibility; a change in instrumentation specification which minimizes interference and/or optimizes instrument performance (if the use of such interference reduction technique or performance enhancement is required); a change in calibration guidance which results in more restrictive recommendations; a change that institutes tighter QC recommendations; or a change in the reagents that are required by the method.

ORCR understands revisions are sometimes necessary to either enhance the performance of the method or to allow flexibilities due to the complexity of sample matrices. In situations where the user is not certain whether the selected method, method modification or modification to their plan is appropriate, EPA recommends the regulated community seek approval from the appropriate regulatory agency (e.g., Federal or State/local government, client) before their use of a revised method; amend their plan (e.g., Project Plan, Quality Assurance Project Plan (QAPP), Sampling and Analysis Plan (SAP), Standard Operating Procedure (SOP)); and properly document the change when reporting analytical results.

The following method status definitions reflect the current method development process and have been developed to add clarity for the method users. ORCR uses these definitions and the terms may vary for other program offices.

Final Method—A method that has been formally adopted into the most recent version of the SW-846 compendium. Before a method becomes final, the validated version would have been made available for public review and comment in a Notice of Availability (NOA) or a proposed rulemaking, as appropriate.

Validated Method—A method that has undergone development and technical review by EPA, but has not been formally adopted into the SW-846 method compendium and published through a Federal Register Notice. Since this review includes technical work group approval and/or inter-laboratory validation, validated methods are included on the Agency Web site for evaluation and use by the public and as a means of soliciting comment from the broader scientific community. The public may use a validated method prior to its inclusion in the SW-846 compendium, provided that the users demonstrate that it generates data that are appropriate for the intended use.

Revised Method—A method included in SW-846 that has been updated to reflect changes that may be editorial in nature and do not impact data or performance comparability, that broaden the method to introduce new technologies that may increase productivity, but do not change the fundamental technology, or that change the quality control requirements to increase bias or precision.

The number of a method that has been revised does not change, but the method may receive a subsequent letter suffix. If the revision is a significant one (as defined above) then both the letter suffix and the issuance date are updated. If, on the other hand, the revision is editorial in nature, or consists of the addition of new performance data, then only the issuance date is changed. Previous versions are not precluded from being used provided that the users demonstrate that it generates data that are appropriate for the intended use.

Draft Method—A new method that is being evaluated for possible inclusion into SW-846. It represents the latest innovative technological advancements in scientific methodology, but has not completed technical review by EPA nor been subject to notice and comment in the Federal Register.

Superseded Method—A superseded method is an earlier version of an SW-846 method or other guidance that is no longer included in the SW-846 compendium and has been replaced by a newer version. Revised versions of Superseded methods should be viewed as the preferred method. Methods in this category are removed from the compendium, but remain available on line and are not precluded for use where required for existing projects or where an adequate justification for use exists. The term

“Superseded” is documented in the method title as listed on the EPA Web site for prior versions of final methods followed by the date it was superseded.

Withdrawn Method—A method or other guidance that EPA strongly recommends not be used, (e.g., cyanide and sulfide reactivity guidance withdrawn, June 14, 2005). EPA has determined that such procedures or methods, for the use or technical objectives for which they were originally published, are technically inadequate and/or no longer meet such use or technical objectives. This does not mean, however, that there would be no situations under which the procedures or methods may be appropriate. In any situation in which a person may believe that the withdrawn method is appropriate, we strongly encourage consultation with applicable regulatory agencies at the state or federal level. The prospective user of the method will need to demonstrate the old method is, indeed, appropriate. Any use of these methods, without any such consultation and demonstration, will be done at the user’s risk.

The Agency understands that earlier versions of the SW-846 methods that aren’t required may still be in use to meet project specific criteria (e.g., permits, sampling plans, Consent Decrees, etc.). Permits and other plans formally approved by regulatory authorities that specify the use of particular methods for required analysis continue in effect unless they are changed. However, the Agency encourages the regulated community to use the latest version of SW-846, when applicable. EPA will continue to update the Methods Status Table to inform the public as to the status of methods in SW-846 and the Policy Statement will be added to the SW-846 methods compendium when the Update V package is finalized.

[end of policy statement]