

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 143.4(b)

Contaminant	Methodology	EPA Method	ASTM <sup>4</sup>	SM 21st edition <sup>1</sup>	SM Online <sup>3</sup>
Sulfate	Ion Chromatography			4110 B	
	Gravimetric with ignition of residue			4500-SO <sub>4</sub> <sup>-2</sup> C	4500-SO <sub>4</sub> <sup>-2</sup> C-97
	Gravimetric with drying of residue			4500-SO <sub>4</sub> <sup>-2</sup> D	4500-SO <sub>4</sub> <sup>-2</sup> D-97
	Turbidimetric method		D 516-07	4500-SO <sub>4</sub> <sup>-2</sup> E	4500-SO <sub>4</sub> <sup>-2</sup> E-97
	Automated methylthymol blue method			4500-SO <sub>4</sub> <sup>-2</sup> F	4500-SO <sub>4</sub> <sup>-2</sup> F-97

<sup>1</sup> Standard Methods for the Examination of Water and Wastewater, 21st edition (2005). Available from American Public Health Association, 800 I Street, NW, Washington, DC 20001-3710.

<sup>2</sup> EPA Method 200.5, Revision 4.2. "Determination of Trace Elements in Drinking Water by Axially Viewed Inductively Coupled Plasma-Atomic Emission Spectrometry." 2003. EPA/600/R-06/115. (Available at <http://www.epa.gov/nerlcwww/ordmeth.htm>.)

<sup>3</sup> Standard Methods Online are available at <http://www.standardmethods.org>. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.

<sup>4</sup> Available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959 or <http://astm.org>. The methods listed are the only alternative versions that may be used.

<sup>6</sup> Standard Methods for the Examination of Water and Wastewater, 20th edition (1998). Available from American Public Health Association, 800 I Street, NW., Washington, DC 20001-3710.

<sup>10</sup> Mitchell Method M5271, Revision 1.1. "Determination of Turbidity by Laser Nephelometry," March 5, 2009. Available at <http://www.nemi.gov> or from Leck Mitchell, Ph.D., PE, 656 Independence Valley Dr., Grand Junction, CO 81507.

<sup>11</sup> Mitchell Method M5331, Revision 1.1. "Determination of Turbidity by LED Nephelometry," March 5, 2009. Available at <http://www.nemi.gov> or from Leck Mitchell, Ph.D., PE, 656 Independence Valley Dr., Grand Junction, CO 81507.

<sup>12</sup> Orion Method AQ4500, Revision 1.0. "Determination of Turbidity by LED Nephelometry," May 8, 2009. Available at <http://www.nemi.gov> or from Thermo Scientific, 166 Cummings Center, Beverly, MA 01915, <http://www.thermo.com>.

<sup>13</sup> Modified Colitag™ Method, "Modified Colitag™ Test Method for the Simultaneous Detection of *E. coli* and other Total Coliforms in Water (ATP D05-0035)," August 28, 2009. Available at <http://www.nemi.gov> or from CPI, International, 580 Skylane Boulevard, Santa Rosa, CA 95403.

<sup>14</sup> EPA Method 557. "Determination of Haloacetic Acids, Bromate, and Dalapon in Drinking Water by Ion Chromatography

Electrospray Ionization Tandem Mass Spectrometry (IC-ESI-MS/MS)," August 2009. EPA 815-B-09-012. Available at [http://epa.gov/safewater/methods/analyticalmethods\\_ogwdw.html](http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html).

<sup>15</sup> AMI Turbiwell, "Continuous Measurement of Turbidity Using a SWAN AMI Turbiwell Turbidimeter," August 2009. Available at <http://www.nemi.gov> or from Markus Bernasconi, SWAN Analytische Instrumente AG, Stubbachstrasse 13, CH-8340 Hinwil, Switzerland.

<sup>16</sup> EPA Method 334.0. "Determination of Residual Chlorine in Drinking Water Using an On-line Chlorine Analyzer," August 2009. EPA 815-B-09-013. Available at [http://epa.gov/safewater/methods/analyticalmethods\\_ogwdw.html](http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html).

<sup>17</sup> ChloroSense. "Measurement of Free and Total Chlorine in Drinking Water by Palintest ChloroSense," September 2009. Available at <http://www.nemi.gov> or from Palintest Ltd, 21 Kenton Lands Road, PO Box 18395, Erlanger, KY 41018.

<sup>18</sup> EPA Method 302.0. "Determination of Bromate in Drinking Waters using Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection," September 2009. EPA 815-B-09-014. Available at [http://epa.gov/safewater/methods/analyticalmethods\\_ogwdw.html](http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html).

<sup>19</sup> EPA 415.3, Revision 1.2. "Determination of Total Organic Carbon and Specific UV Absorbance at 254 nm in Source Water and Drinking Water," August 2009. EPA/600/R-09/122. Available at <http://www.epa.gov/nerlcwww/ordmeth.htm>.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**42 CFR Part 52**

[Docket No. NIH-2007-0929]

RIN 0925-AA42

**Grants for Research Projects**

**AGENCY:** National Institutes of Health, Department of Health and Human Services.

**ACTION:** Final rule.

**SUMMARY:** The National Institutes of Health is amending the current regulations governing grants for research projects by revising the definition of Principal Investigator to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of Principal Investigator to one single individual; and the conditions for multiple or concurrent awards pursuant to one or more applications.

**DATES:** This final rule is effective December 10, 2009.

**FOR FURTHER INFORMATION CONTACT:** Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852-7669, or telephone 301-496-4607.

**SUPPLEMENTARY INFORMATION:** On September 30, 2003, the NIH Director announced a series of far reaching strategic initiatives known collectively as the NIH Roadmap for Medical Research (NIH Roadmap). The NIH Roadmap is an innovative approach designed to transform the Nation's medical research capabilities and accelerate fundamental research discovery and translation of that knowledge into effective prevention strategies and new treatments. One of the NIH Roadmap initiatives encourages interdisciplinary research and team science and includes a recommendation to modify grant and research contract applications to allow for the proposing of more than one Principal Investigator when appropriate. This is congruent with the January 4, 2005, directive issued by the Office of Science and Technology Policy (OSTP) to all Federal research agency heads instructing the heads to accommodate the recognition of two or more Principal Investigators on research projects (grants and contracts). This OSTP policy does not prohibit the use of a single Principal

Investigator when that is most appropriate for a particular research project; it simply permits the designation of one or more than one Principal Investigator when that more accurately reflects the management needs of a research project.

For the purpose of implementing the NIH Roadmap initiatives, now known as the Common Fund, the NIH plans to modify research grant and contract applications to request information on more than one Principal Investigator, consistent with the OSTP policy establishing the appropriateness of multiple Principal Investigators. Accordingly, we are revising the definition of the term Principal Investigator set forth in section 52.2 of the Grants for Research Projects regulations, codified at 42 CFR part 52, so that it does not limit the role of Principal Investigator to one single individual, and the conditions for multiple or concurrent awards set forth in section 52.6, paragraph (d) of the Grants for Research Projects regulations, codified at 42 CFR part 52, to permit the Secretary to evaluate, approve, and make one or more awards pursuant to one or more applications.

As announced in NIH notice number OD-07-017 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html>), these individuals must be judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant in order to be considered Principal Investigators. While this rule permits the applicant organization to designate multiple individuals as Principal Investigators who share the authority and responsibility for leading and directing the project, intellectually and logistically, each Principal Investigator is responsible and accountable to the applicant organization (or as appropriate, to a collaborating organization) for the proper conduct of the project or program, including the submission of all required reports. In other words, the presence of more than one identified Principal Investigator on an application or award diminishes neither the responsibility nor the accountability of any individual Principal Investigator.

Additionally, under current regulations, the Secretary is permitted to evaluate, approve, and make more than one award pursuant to two or more applications. In some cases, however, it may be desirable to disaggregate a single application to make more than one award. For example, in the case of an application for support of a project that involves more than one Principal

Investigator affiliated with more than one institution, it may be desirable to administer the project with more than one award. In addition, applications that involve subprojects may be disaggregated into separate awards to improve scientific management.

The revised regulatory language clarifies options and provides an opportunity to contemplate more than one award that may involve more than one institution in response to a single application. In some of these cases, separate records will be associated in the NIH data system so that the components can be managed as a single project to promote close collaboration with their counterparts. Actual awards also will be associated through special terms of award to clearly note collaborations and any special requirements resulting from such collaborations. In other cases, it may be appropriate to consider multiple applications from more than one institution that are managed as a single unit, with multiple awards to the different institutions to facilitate collaboration.

We believe this change will foster interdisciplinary and collaborative research and will improve management flexibility even when components of such collaborative research programs are administered by different NIH awarding components.

On June 25, 2007, we published a Notice of Proposed Rulemaking in the **Federal Register** (72 FR 34655-34657) in which we announced our intention to amend the current regulations governing NIH grants for research projects, as previously discussed, and solicited public comment. We provided for a 60-day comment period. We received comments from 11 separate individuals and institutions concerning various aspects of the NPRM. Most comments supported NIH's proposed actions. However, several comments raised concerns about the actions. In order to make it easier to identify comments and NIH's responses to the comments, the word "Comment" appears in parentheses before the description of the comment, and the word "Response" appears in parentheses before NIH's response.

(Comment) Three commenters indicated that having multiple PIs on a research grant would result in many disputes, some of which would need to be resolved by NIH. They suggested that one person will always have the vision that guides the study and that having additional PIs could lead to confusion and diffuse authority and could result in a team that is less productive. They

indicated that NIH should not permit more than a single PI.

(Response) The NIH believes there are many projects that already involve collaboration at the leadership level. Also, there are many projects that cannot be accomplished without a partnership between individuals with different disciplinary or experimental backgrounds. Offering the option of having more than one PI will enable all members of the leadership team to be recognized for their respective contributions. It is not clear to us that there will be more disputes in a partnership setting than there would be in a more hierarchical setting. However, each multiple PI application must include a leadership plan that establishes an approach for dispute resolution. This approach has been used successfully for many years in the administration of program project and center grants, which involve more than one research component. Furthermore, NIH will not require all projects to include more than one PI. The NIH is offering this management approach as an option to more effectively credit partnering collaborators.

(Comment) One commenter stated that allowing multiple PIs will permit more senior investigators to take money away from junior collaborators.

(Response) The issue of inequities between junior and senior collaborators is an issue that all institutions need to consider. The NIH believes that in cases of a true partnership, recognizing the names of both junior and senior collaborating PIs will offer an opportunity to reduce any power differential that might exist with respect to the project or within the grantee organization. It is not clear how making this option available would allow more senior investigators to take money away from junior collaborators.

(Comment) One commenter supported the proposed revision of the definition of the term "Principal Investigator" in section 52.2. However, the same commenter was concerned that institutions should be consulted if NIH decides to make more than one award in response to a single application (section 52.6).

(Response) We agree with the second comment that NIH should consult with institutions when it decides to make more than one award in response to a single application (section 52.6). Over the years NIH has occasionally disaggregated complex multiple project awards into separate, single project awards when the individual projects have appeared to be more meritorious than the combined, multicomponent approach. In all such cases, NIH

consulted the grantee institution(s) before such awards were made. We agree with the proposal and have modified the language set forth in section 52.6 to read as follows: “\* \* \* [T]he Secretary may evaluate, approve, and make one or more awards pursuant to one or more applications. When making more than one award in response to a single application, the Secretary shall consult with the applicant organization(s), as appropriate.”

(Comment) One commenter was concerned that the rationale for disaggregating single applications into several awards was not fully articulated. The commenter believed that it could have utility in the case of a project that involved collaborating PIs at different institutions, which could be supported through multiple, linked awards, but in the view of the commenter, this was not sufficiently explained in the final rule.

(Response) The commenter provided an important point. As previously indicated, NIH has experience in disaggregating complex awards into one or more discrete projects when the individual projects are more meritorious than the combined, complex project. In the case of collaborative applications for a single project that involves more than one institution, it may be ideal from a management perspective to make more than one award that is linked to fund the remote parts of the project. The alternative and more commonly employed approach is to make a single award to one of the institutions and to manage the parts of the project that occur at a separate institution through a sub-award. The NIH has used both approaches. Presently, NIH is not in a position to consider large numbers of collaborative applications that involve multiple institutions or to manage a large number of linked awards. Nonetheless, the change in the final rule will permit such management approaches in the future.

(Comment) One commenter supported the proposal to allow multiple PIs and multiple awards in response to a single application.

(Comment) One commenter supported the proposed redefinition of the term Principal Investigator and the language which permits the evaluation approval and issuance of more awards pursuant to one or more grant applications.

(Comment) One commenter supported the proposed rule, indicating that it will encourage collaboration and will facilitate the management, oversight, and stewardship of Federal funds.

(Comment) One commenter supported the proposed revision of the definition of “Principal Investigator,” indicating

that it will preserve the role, authority and responsibility of all collaborating PIs.

(Comment) One commenter fully supported expanding the position of Principal Investigator as proposed, indicating that it will better reflect the intellectual leadership of many NIH grants.

(Comment) One commenter indicated that the designation of multiple Principal Investigators is an excellent idea, noting that it will be beneficial for young investigators who frequently get “second billing” on a proposal because of the feeling that a senior colleague is more likely to be funded.

(Comment) One commenter stated that having the ability to make more than one award to recognize collaborating institutions will improve the business process for collaborating institutions, although this was not specifically mentioned in the NPRM.

We provide the following as public information.

#### **Regulatory Flexibility Act**

The Regulatory Flexibility Act of 1980 (5 U.S.C. chapter 6) requires that regulatory actions be analyzed to determine whether they create a significant impact on a substantial number of small entities. The Director, NIH, certifies that this final rule does not have such impact.

#### **Executive Order 12866**

Executive Order 12866, “Regulatory Planning and Review,” requires that all regulatory actions reflect consideration of the costs and benefits they generate and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If a regulatory action is deemed to fall within the scope of the definition of the term “significant regulatory action” contained in section 3(f) of Executive Order 12866, prepublication review by the Office of Management and Budget (OMB)’s Office of Information and Regulatory Affairs (OIRA) is necessary. This final rule was reviewed under Executive Order 12866 by OIRA and was deemed significant.

Executive Order 12866 also requires each agency to write all rules in plain language. With this in mind, we have made every effort to make this rule easy to understand.

#### **Executive Order 13132**

Executive Order 13132, Federalism, requires that Federal agencies consult with State and local government officials in the development of regulatory policies with Federalism implications. The Director, NIH, has

reviewed this final rule and as required has determined that it does not have any Federalism implications. The Director, NIH, certifies that the final rule will not have an effect on the States, or on the distribution of power and responsibilities among the various levels of government.

#### **Unfunded Mandates Act of 1995**

This final rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$12,000,000 or more [adjusted for inflation] in any one year and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the Unfunded Mandates Act of 1995.

#### **Paperwork Reduction Act**

This final rule contains information collection requirements that were approved under OMB 0925–0001 in April 2006.

#### *The Catalogue of Federal Domestic Assistance*

*The Catalogue of Federal Domestic Assistance* numbered programs that are affected by the final rule include the following:

- 93.113—Biological Response to Environmental Health Hazards
- 93.114—Applied Toxicological Research and Testing
- 93.115—Biometry and Risk Estimation—Health Risks from Environmental Exposures
- 93.118—Acquired Immunodeficiency Syndrome (AIDS) Activity
- 93.121—Oral Diseases and Disorders Research
- 93.135—Centers for Research and Demonstration for Health Promotion and Disease Prevention
- 93.136—Injury Prevention and Control Research and State and Community Based Programs
- 93.172—Human Genome Research
- 93.173—Research Related to Deafness and Communication Disorders
- 93.184—Disabilities Prevention
- 93.213—Research and Training in Complementary and Alternative Medicine
- 93.242—Mental Health Research Grants
- 93.262—Occupational Safety and Health Program
- 93.271—Alcohol Research Career Development Awards for Scientists and Clinicians
- 93.273—Alcohol Research Programs
- 93.279—Drug Abuse and Addiction Research Programs
- 93.281—Mental Health Research Career/Scientist Development Awards
- 93.283—Centers for Disease Control and Prevention—Investigations and Technical Assistance
- 93.361—Nursing Research
- 93.389—National Center for Research Resources

93.390—Academic Research Enhancement Award  
 93.393—Cancer Cause and Prevention Research  
 93.394—Cancer Detection and Diagnosis Research  
 93.395—Cancer Treatment Research  
 93.396—Cancer Biology Research  
 93.701—Trans-NIH Recovery Act Research Grant  
 93.702—NCRR Recovery Act Construction Support  
 93.821—Biophysics and Physiological Sciences Research  
 93.827—Heart and Vascular Diseases Research  
 93.838—Lung Diseases Research  
 93.839—Blood Diseases and Resources Research  
 93.846—Arthritis, Musculoskeletal and Skin Diseases Research  
 93.847—Diabetes, Endocrinology and Metabolism Research  
 93.848—Digestive Diseases and Nutrition Research  
 93.849—Kidney Diseases, Urology and Hematology Research  
 93.853—Clinical Research Related to Neurological Disorders  
 93.855—Allergy, Immunology and Transplantation Research  
 93.856—Microbiology and Infectious Diseases Research  
 93.859—Biomedical Research and Research Training  
 93.865—Research for Mothers and Children  
 93.866—Aging Research  
 93.867—Vision Research  
 93.879—Medical Library Assistance  
 93.929—Center for Medical Rehabilitation Research  
 93.934—Fogarty International Center Research Collaboration Award  
 93.939—Blood Diseases and Resources Research  
 93.941—HIV Demonstration, Research, Public and Professional Education Projects  
 93.942—Research, Treatment and Education Programs on Lyme Disease in the United States  
 93.943—Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups  
 93.947—Tuberculosis Demonstration, Research, Public and Professional Education

#### List of Subjects in 42 CFR Part 52

Grant programs—Health, Medical research, Occupational safety and health.

Dated: July 21, 2009.

**Raynard S. Kington,**

*Director, National Institutes of Health.*

Approved: September 22, 2009.

**Kathleen Sebelius,**

*Secretary.*

■ For reasons presented in the preamble, we amend Part 52 of Title 42 of the Code of Federal Regulations as set forth below.

## PART 52—GRANTS FOR RESEARCH PROJECTS

■ 1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 216.

■ 2. We amend § 52.2 by revising the definition of the term “Principal investigator” to read as follows:

### § 52.2 Definitions.

\* \* \* \* \*

*Principal investigator* means the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant and who is or are responsible for the scientific and technical direction of the project.

\* \* \* \* \*

■ 3. We amend § 52.6 by revising paragraph (d) to read as follows:

### § 52.6 Grant awards.

\* \* \* \* \*

(d) *Multiple or concurrent awards.* Whenever a research project involves a number of different but related problems, activities or disciplines which require evaluation by different groups, or whenever support for a project could be more effectively administered by separate handling of separate aspects of the project, the Secretary may evaluate, approve, and make one or more awards pursuant to one or more applications. When making more than one award in response to a single application, the Secretary shall consult with the applicant organization(s), as appropriate.

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### 44 CFR Part 65

[Docket ID FEMA-2008-0020; Internal Agency Docket No. FEMA-B-1063]

### Changes in Flood Elevation Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Interim rule.

**SUMMARY:** This interim rule lists communities where modification of the Base (1% annual-chance) Flood Elevations (BFEs) is appropriate because

of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

**DATES:** These modified BFEs are currently in effect on the dates listed in the table below and revise the Flood Insurance Rate Maps (FIRMs) in effect prior to this determination for the listed communities.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the FEMA Assistant Administrator for Mitigation reconsider the changes. The modified BFEs may be changed during the 90-day period.

**ADDRESSES:** The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

#### FOR FURTHER INFORMATION CONTACT:

Kevin C. Long, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2820.

**SUPPLEMENTARY INFORMATION:** The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based on knowledge of changed conditions or new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain