Quality Assurance Plan
for HUD Healthy Homes and Lead Technical Studies
Grantees and Contractors

TEMPLATE

VERSION 2.1

November 2005

PREFACE

HUD Healthy Homes Initiative (HHI) and Lead Technical Studies grantees and contractors should develop a Quality Assurance Plan (QA Plan), in accordance with HUD and OMB Information Quality Guidelines (IQG), before collecting any data for their grant. The attached template has been written to assist grantees and contractors in developing the QA Plan. This template can be downloaded from HUD's Office of Healthy Homes and Lead Hazard Control website (www.hud.gov/offices/lead).

Standard text is provided throughout each section of this QA Plan template. Grantees and contractors should modify the text as appropriate to fit the needs of their organization and project. The specific writing responsibilities of the grantee or contractor are highlighted in ***bold italics*** throughout this document. If a particular sub-section is not applicable to the project, a sentence to this effect should be provided in the sub-section (that is, the sub-section should not be deleted).

The QA Plan is made up of four sections. The first, "Project Management," contains information on management of the project, including personnel, data, and records. The second, "Measurement/Data Acquisition," provides detailed plans for the collection of the data. In the third section, "Assessment/Oversight," such assessment activities as audits, corrective actions, and reports to management are described. Finally, the fourth section, "Data Verification and Usability," outlines the checks and verification activities that will be performed to ensure that the collected data are of the expected quality to meet the grant's objectives.

The Data Quality Objectives (DQOs) specified in Section 1.5 are a very important part of the QA Plan. They are used to establish quality control measures (described in Section 2.5) and data verification procedures (described in Section 4.2). Each Section addresses a different component of the DQOs. This assures that the user objectives are considered throughout the study so that the resulting data are of the desired quality.

This template is a streamlined version of the U.S. Environmental Protection Agency (EPA) Quality Assurance Project Plan (QAPP) guidelines. EPA's Office of Environmental Information website (www.epa.gov/quality) can be consulted for additional information on implementing quality assurance programs and writing quality assurance documents. Specifically, the EPA *Requirements for Quality Assurance Project Plans for Environmental Data* (EPA publication QA/R-5), and *Guidance for Quality Assurance Project Plans* (EPA publication QA/G-5) documents, which provide EPA requirements and guidance on writing QAPPs, can be downloaded from this website. Note that the EPA QA/R-5 document contains a good glossary of quality assurance (QA) and quality control (QC) terms used throughout this template. Examples of actual QAPPs also can be found on EPA's website.

[Insert Title of Specific Project]

[Insert Organization Name and Address]

[Insert Grant or Contract/Task Order Number]

Approval for ***[Insert Name of Organization]:***

_____

Principal Investigator

Date

[Insert Name]

Approval for HUD Office of Healthy Homes and Lead Hazard Control:

_____

Date

[Insert Name]

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APPENDICES

[Note: Add additional appendices as needed]

1.0 PROJECT MANAGEMENT

1.1 DISTRIBUTION LIST

Individuals who will receive copies of the approved QA Plan and any subsequent revisions are listed in Table 1-1. Each individual's role on the project and the organization to which he/she belongs also are provided. Note that "HUD OHHLHC" is the abbreviation for HUD's Office of Healthy Homes and Lead Hazard Control, and "HUD GTR" refers to the HUD Government Technical Representative for the grant.

Table 1-1. Distribution List for QA Plan

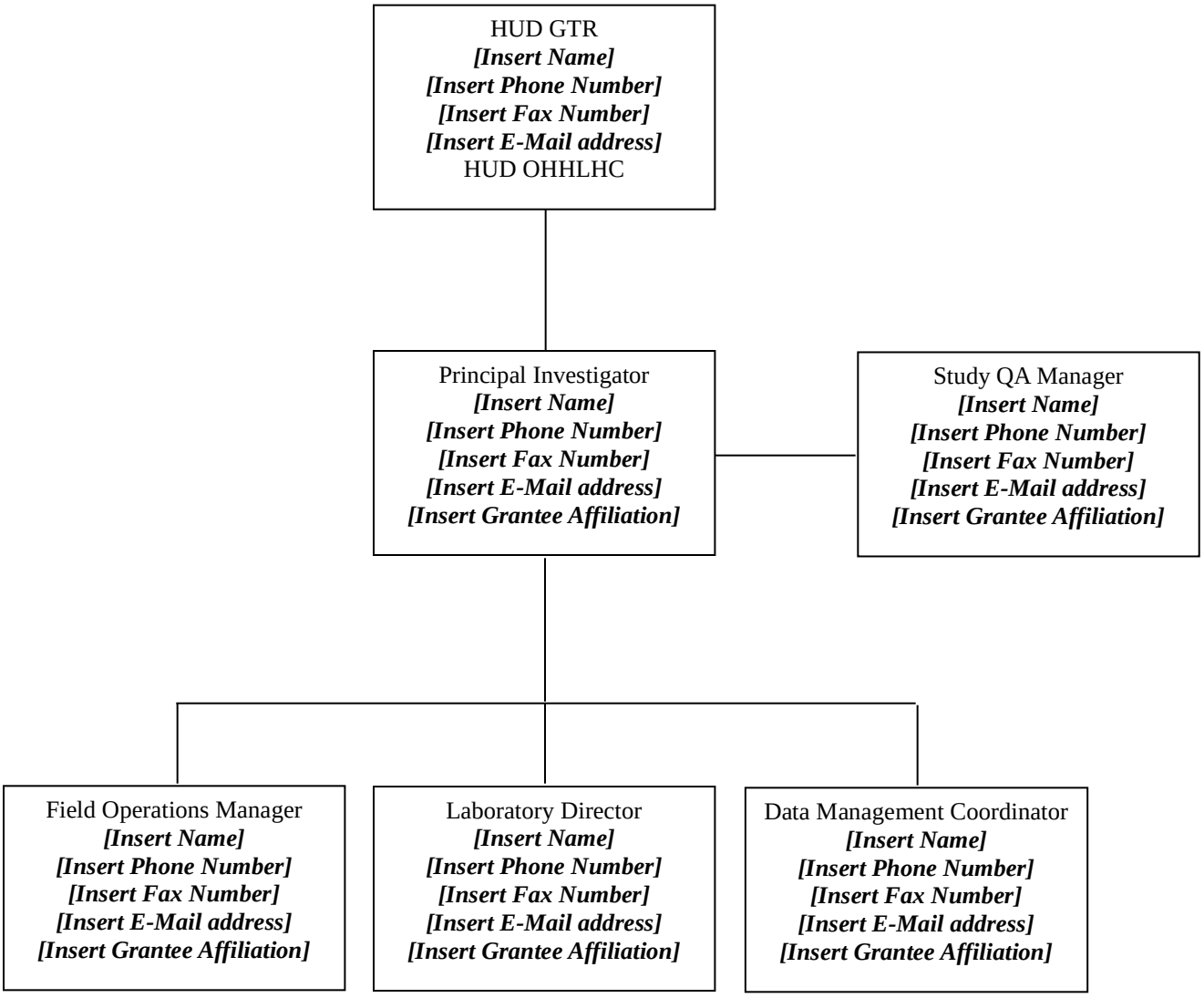
Individual	Organization	Project Responsibility / Role
	HUD OHHLHC	HUD GTR
		Principal Investigator
		Quality Assurance Manager
		Field Operations Manager
		Laboratory Director
		Data Management Coordinator

[Grantees and contractors should include all persons who are responsible for implementation of the project, including managers, QA managers, and representatives of all groups involved. Examples of the types of people to include are provided in the table. Grantees and contractors should add to and delete from this table as appropriate for their individual project. Responsible managers also should be added to the approval page preceding the Table of Contents.]

1.2 PROJECT ORGANIZATION

[Insert name of principal investigator] will have overall responsibility for this study. The individuals who will assist the principal investigator are listed below, followed by a brief description of their responsibilities. Figure 1-1 displays the organizational relationships among these individuals.

[Grantees and contractors should use the example organizational chart as a guide, adding or deleting individuals as necessary for the project. Grantees and contractors will identify all individuals or organizations participating in the project and briefly describe their specific roles and responsibilities. Grantees and contractors should ensure that the study QA manager is independent of the organizational unit that is generating the data. Grantees and contractors should provide an organizational chart showing relationships and lines of responsibility and communication among project participants, data users outside the organization generating the data, and any subcontractors, subgrantees and subcontractors involved in collecting or processing data.]



INSERT Figure 1-1.

Organizational Structure for *[Insert Organization Name, Grant Name, Grant or Contract/Task Order Number]*

1.3 PROBLEM DEFINITION/BACKGROUND

[Provide a one-paragraph summary on the background of the technical studies that will be performed. Discuss the reasons for undertaking the project. It is likely that much of the background write-up can be taken from the grant proposal accepted by HUD. Sample language is provided below for several projects.]

[Sample language for an asthma/allergen related study] More than 17 million persons in the United States are estimated to have asthma (CDC, 1998a), and among children, it is the most common chronic illness (NAS, 2000). Furthermore, a substantial body of research, including population-based studies of school-aged children and young adults, indicates that the prevalence and severity of asthma have increased dramatically over the last several decades (CDC, 1998b). These increases in asthma prevalence and severity have occurred despite general reductions in levels of most air pollutants outdoors; therefore, many researchers instead point to coinciding changes in the home environment as potentially important, and possibly more important, factors in determining asthma risk. The strongest established risk factors for development of asthma are family history of allergic disease and sensitization (development of an allergic reaction) to one or more indoor allergens. Common indoor allergen sources include dust mites, cockroaches, animals (domestic animals and pests such as rodents), and mold. Research also indicates that other factors can exacerbate asthma symptoms, such as respiratory tract infections, bacterial endotoxins, indoor pollutants (environmental tobacco smoke, nitrogen oxides/indoor combustion products, formaldehyde, VOCs, pesticides), and outdoor pollutants that penetrate the indoor environment (sulfur oxides, ozone, particulate matter). [Sources: CDC. 1998a. *Forecasted State-Specific Estimates of Self-Reported Asthma Prevalence -- United States, 1998*. MMWR. December 4, 1998: 47(47); 1022-1025; CDC. 1998b. *Surveillance for asthma-United States, 1960-1995*. In: CDC Surveillance Summaries, MMWR. April, 1998: 47(no. SS-1); NAS. 2000. *Clearing the Air: Asthma and Indoor Air Exposures*. National Academy of Sciences Institute of Medicine, Division of Health Promotion and Disease Prevention. National Academy Press, Washington, D.C. 438 pp.]

[Sample language for a study focusing on mold] People are routinely exposed indoors and outdoors to over 200 species of mold (NAS, 2000). Molds are usually saprophytes (i.e., they feed on dead organic matter) and, when provided with sufficient moisture, can live off of many materials found in homes, such as wood, cellulose in the paper backing on drywall, insulation, wallpaper, glues used to bond carpet to its backing, and everyday dust and dirt. Research indicates that certain molds can cause a variety of adverse human health effects, including allergic reactions and immune responses (e.g., asthma), infectious disease (e.g., histoplasmosis), and toxic effects (e.g., aflatoxin-induced liver cancer) (ACGIH, 1999). Molds are thought to play a role in asthma in several ways. They are known to produce a large number of compounds that are potentially allergenic, and there is sufficient evidence to support associations between fungal allergen exposure and asthma exacerbation and upper respiratory disease (NAS, 2000). In addition, molds may play a role in asthma via release of irritants that increase potential for

sensitization, or release of toxins (mycotoxins) that affect immune response (NAS, 2000). Finally, mold toxins can cause direct lung damage leading to pulmonary diseases other than asthma (NAS, 2000). [Sources: ACGIH. 1999. *Bioaerosols: Assessment and Control*. (J. Macher, ed.). American Conference of Governmental and Industrial Hygienists, Cincinnati, Ohio; NAS. 2000. *Clearing the Air: Asthma and Indoor Air Exposures*. National Academy of Sciences Institute of Medicine, Division of Health Promotion and Disease Prevention. National Academy Press, Washington, D.C. 438 pp.]

[Sample language for a study focusing on carbon monoxide] Carbon monoxide (CO) is a colorless, odorless, and poisonous gas that is produced as a by-product of incomplete combustion of carbon-based fuels such as natural or liquefied propane (LP) gas, oil, wood, or coal. When inhaled, CO readily combines with oxygen-binding proteins in the bloodstream (e.g., with hemoglobin to form carboxyhemoglobin). This interferes with oxygen being carried to the tissues and organs of the body, and leads to adverse health effects, such as neurological impairment, and eventually, at high enough levels, causes death by asphyxiation. Although unintentional CO deaths have decreased steadily over the past decade, an estimated 11,000 people were treated in emergency rooms for suspected non-fire carbon monoxide poisoning in 1997 (NSC, 2000). According to the Consumer Product Safety Commission, between 1991 and 1995, the total number of unintentional non-fire CO poisoning deaths averaged about 560 annually (NSC, 2000). The majority (66%) of these deaths occurred in the home. In the home, major sources of CO include tobacco smoke, combustion appliances that are either unvented (e.g., gas or kerosene space heaters) or that have improperly installed or malfunctioning ventilation, and vehicle start-up and idling in attached garages. CO levels also can become elevated in buildings where backdrafting is occurring as a result of a constricted or poorly functioning chimney; improperly designed or maintained venting systems; or other house depressurization created by the operation of household equipment such as exhaust fans, clothes dryers, and fireplaces. [Sources: National Safety Council, *Injury Facts 2000 edition*]

[Sample language for a study focusing on lead] Lead poisoning is a continuing environmental health concern in the United States. Reductions in blood-lead levels have been achieved through efforts to remove lead from gasoline, food cans, and other consumer products. However, the threat of lead poisoning still exists today through exposure to lead-based paint. HUD estimates that 38 million homes contain lead-based paint, and 26 million of these homes have significant lead-based paint hazards (HUD, 2001). The primary concern with lead-based paint is that paint dust is harmful when swallowed, especially by children under the age of six. When ingested, lead can affect children's developing nervous systems, resulting in learning disabilities and a reduced IQ. [Sources: HUD. 2001. *National Survey of Lead and Allergens in Housing*. Office of Healthy Homes and Lead Hazard Control, U.S. Department of Housing and Urban Development.]

1.4 PROJECT DESCRIPTION, OBJECTIVES, AND SCHEDULE

[Provide a one-page project description. In many cases, the project description and objectives can be taken from the grant work plan accepted by HUD. Alternatively, use the text/instructions provided below to describe the project and how it will be conducted.]

This project will be conducted to investigate activities on housing-related health and safety issues. ***[Add a sentence or two describing the specific HHI or lead activity being studied]*** The study will be conducted over a ***[insert study length]*** period beginning in ***[insert start month/year]***. The following paragraphs describe the work that will be performed.

[Provide an overall, concise description of the project. Include project objectives; measurements to be made; applicable technical, regulatory or program-specific quality standards, criteria, or objectives; any special personnel and equipment requirements; assessment tools needed; and project and quality records required, including the types of reports needed.]

[If the study involves the collection of data from the general public, discuss the process for working with HUD to obtain any required approval from the U.S. Office of Management and Budget (OMB). (Note: This is not required for grantees. You should check with your GTR or GTM if you have any question regarding the need to obtain OMB approval .)]

[If the study fits the broad definition of human subject research (as defined by the Department of Health and Human Services (45 CFR 46)), indicate whether IRB approval has been obtained (see section 1.8, below)).]

The schedule for completing the various tasks associated with this study is illustrated in Figure 1-2. ***[Briefly discuss key milestones and how they fit into the schedule. The schedule can be portrayed by inserting the project's benchmark spreadsheet. (The financial information can be omitted. Templates and sample benchmark spreadsheets are at the OHHLHC website, www.hud.gov/offices/lead.) Figure 1-2 below is another example of how this schedule can be portrayed. Grantees and contractors should tailor the schedule to fit the project's needs, adding to, or deleting from, the sample project activities as necessary, and should portray the schedule in whatever visual format they wish (i.e., not necessarily the example "table" format).]***

Project Activity	Activity Period (Months After Project Initiation)								
	0	3	6	9	12	15	18	21	24
Study Design, Develop QA Plan	(----)								
OMB/IRB Approval		(-------)							
Enrollment of participants			(----------)						
Sample Collection			(----------)						
Laboratory Analysis			(----------)						
Database Management			(----------)						
Statistical Analysis						(----------)			
Report Writing								(----------)	

Figure 1-2. Schedule of Accomplishments and Milestones

1.5 QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT DATA

The objectives of this study are described in Section 1.4. These objectives will be addressed by collecting data on ***[specify a brief description of types of data measurements]***. In regard to collecting these data, this study is intended to satisfy the following data quality objectives (DQOs).

- ***[Specify DQO 1]***
- ***[Specify DQO 2]***
- ***…***
- ***[Specify DQO n]***

[As described by EPA, DQOs are qualitative and quantitative statements that clarify the study objective; define the most appropriate type of data to collect; determine the most appropriate conditions from which to collect the data; and specify tolerable limits on decision errors which will be used as the basis for establishing the quantity and quality of data needed to support the decision. The DQOs are then used to develop a scientific and resource-effective data collection design.]

[DQOs must clearly spell out how the data collected for the study will be used for decision-making. They may be quantitative or qualitative, depending on the nature of the research. For example, a pilot study to determine the feasibility and acceptance of a new sampling method might specify many qualitative DQOs related to information on ease of use, field technician acceptance, inconvenience to occupants, etc. On the other hand, a study addressing whether a new sampling method provides equivalent results to an established method would require quantitative DQOs addressing accuracy, precision, and the power to detect differences of a specified magnitude. If desired, EPA's "Guidance for the Data Quality Objectives Process" document (QA/G-4) can be consulted for a more technical discussion of DQOs, as well as a description of EPA's 7-step DQO process (www.epa.gov/quality/qs-docs/g4-final.pdf).]

[Points to remember in specifying DQOs include:

1) Clearly state the decision that will be made using the data.

2) ***Clearly state the statistical or non-statistical analysis that will be used as the basis of the decision.***
3) ***Clearly state any minimum data quality requirements for the analysis in #2.***

DQOs should be specified, regardless of whether the study involves data from sampling, surveys, or some other assessment method. Even if the study data will not be used to make specific decisions, DQOs still are necessary to document the systematic planning that occurred in designing the study's data collection procedures. To aid in writing DQOs, a few examples are provided to show the types of quantitative and qualitative statements that can serve as study DQOs.

<u>Sample DQOs</u>:

- ***Based on a survey of residents, establish if a statistically significant correlation exists between knowledge of proper cleaning techniques (as measured by a rating of 1-5 using our knowledge index) and reduced instances of asthma (as measured by self-reported days of work or school due to asthma).***

- ***Based on interviews with field technicians and occupants, determine whether a new field sampling protocol for collecting dust samples is feasible. At least 3 different technicians and 10 occupants must be interviewed. Feasibility will be determined by: no respondents finding the method "excessively burdensome", average sampling time estimated to be less than 1 hour per house, and no safety issues identified.***

- ***Determine whether the lead hazard control interventions performed on the study homes resulted in a statistically significant reduction in average dust-lead levels. This will be assessed by conducting a t-test on the log-transformed data with a minimum of 20 dust samples collected pre- and post-intervention. The observed variability must be such that there is at least 80% power to detect a 50% reduction in dust-lead levels.***

- ***Collect side-by-side dust samples from residential units to determine whether the slope of a relationship between samples analyzed for target allergens by ELISA and by particle immunostaining is significantly different from 1.0 at the 0.05 level of significance, with 80% power.***

- ***Collect dust samples from residential units to determine with 95% confidence whether a unit has an average dust mite level above the exacerbation level of 10 µg/g, thus requiring a hazard control intervention.]***

In addition to the above DQOs, the data to be collected in this study will need to satisfy the following criteria on quality:

[The quality criteria to be presented here represent standards that the collected data need to achieve in order to be acceptable for their particular use on this study. Typically, the QA Plan will specify minimum criteria for such data quality measures as precision, bias, sensitivity, representativeness, completeness, and comparability, although the specific set of quality measures may differ among different types of studies. (These example measures tend to be used most often when collecting and analyzing environmental and biological samples; some of these measures may not be relevant for other types of studies such as surveys or visual inspections.) To help illustrate how to specify minimum criteria on these data quality measures, an example is provided from a study that involves collecting household dust samples for allergen analysis. In place of the example, grantees and contractors should supply appropriate criteria for those quality measures that are applicable to the data to be collected on their study. In doing so, grantees and contractors working with contracted analytical laboratories should contact laboratory representatives to get information on the quality guidelines kept by the laboratories on the data that they will generate. For more information and definitions on measures of data quality, see the EPA "Guidance on Data Quality Indicators" document (QA/G-5i).]

Precision - a measure of agreement among repeated measurements of the same property, under identical or substantially similar conditions. This is the random component of error associated with the measurements; typically expressed as a range, standard deviation, or coefficient of variation. ***At one randomly selected location in each house, side-by-side dust samples will be collected for analysis. Results for these two samples that are above the MDL and have a coefficient of variation greater than 50% and will indicate potential problems with the analytical results for the entire batch of samples (it is also possible that this could be an indication of large spatial variability – both alternatives should be investigated.)]***

Bias - the systematic or persistent distortion of a measurement process that causes error in one direction. It can be determined from measurements associated with blank or spiked samples. ***One field blank sample will be submitted with each batch of collected dust samples. In addition, one field spike sample will be submitted with every 10^{th} batch of samples. Blank samples exceeding the detection limit or spike samples outside ±20% of the known value will indicate potential problems with the analytical results for the entire batch of samples.***

Sensitivity - the capability of a method or instrument to discriminate between measurement responses representing different levels. ***Discrimination will be assessed by examining a control curve containing 11 points. The curve will be formed by analyzing a concentration of 10x the standard and ten additional concentrations created by repeated dilutions by a factor of 2.***

Representativeness - a qualitative term that expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition. ***Samples will be collected from a random sample of houses known by the health department to be inhabited by a child with asthma. Thus, the sample results will represent allergen levels of dust found in study-area homes of a child known to be asthmatic.***

Completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions. ***Valid analytical results for 95% of samples from 95% of the sampled houses are required.***

Comparability - a qualitative term that expresses the measure of confidence with which data from one data set can be compared to another. ***All sampling personnel will receive training in and will use the same sampling protocols (Section 2.2), and field audits will periodically occur to ensure that sampling personnel are following the prescribed protocols. In addition, all samples will be submitted to the same accredited laboratory for analysis by the same method, thus data results will be comparable.***

1.6 SPECIAL TRAINING/CERTIFICATION

The responsibility of addressing training and certification needs will be handled by ***[Grantee should specify person(s) and organizational unit(s) responsible for identifying, ensuring, and documenting that personnel and organizations have and maintain the appropriate knowledge, skill, and statutory, regulatory, professional or other certifications, licenses, or other formal qualification necessary for performing their specific tasks. Specify the accreditation/certification/recognition status of personnel and laboratories used for sampling and/or measurement of analytes (e.g., lead-based paint inspection certification, NLLAP recognition, or EMLAP accreditation). Furthermore, identify and describe any specialized training or certification requirements necessary for conducting this study and discuss how such training will be provided and how the necessary skills will be assured and documented.]***

[In some environmental data operations, special training and/or certification requirements may be necessary in order to ensure the health and safety of field sampling and/or laboratory personnel. Grantees and contractors should consult the following web sites and other relevant sources for information on pertinent training opportunities and guidance, and indicate in this section any procedures that will be implemented and followed to ensure the health and safety of field sampling and laboratory personnel working on this project.

Occupational Safety and Health Administration (OSHA)
www.osha.gov/fso/ote/training/training_resources.html

National Institute for Occupational Safety and Health (NIOSH)
www.cdc.gov/niosh/training.html

U.S. Environmental Protection Agency (EPA)
www.epa.gov/lead/leadcert.htm

American Association for Laboratory Accreditation (A2LA)
www.a2la2.net/training/Courses2003.cfm

American Industrial Hygiene Association (AIHA)
www.aiha.org

[The Grantee or contractor's goal should be to provide a safe working environment for personnel working on the project, whether in the laboratory or in the field, as well as ensuring the safety and care of study subjects and property.]

1.7 DOCUMENTATION AND RECORDS

The following documentation will be maintained in the data records from this study. ***[Grantees and contractors should state the information and records to be included in the data records. Possible records to be included are field operation records (e.g., sample collection records, chain-of-custody records, QC sample records, general field procedures and corrective action reports), survey forms, laboratory records (e.g., sample data, sample management records, test methods, and QA/QC reports), data handling records (e.g., protocols used in data reduction, verification, and validation), and records associated with IRB approval and continuing oversight .]*** These records will be reported in the following formats: ***[Grantees and contractors should state the desired reporting format for hard copy and electronic forms.]***

[Grantees and contractors should identify any other records and documents applicable to the project, such as audit reports, quarterly progress reports, and final reports, that will be produced.

Specify or reference all applicable requirements for the final disposition of records and documents, including location of records and length of retention period.]

1.8 HUMAN SUBJECTS RESEARCH

If the study requires Institutional Review Board (IRB) approval because it involves human research as defined by the Department of Health and Human Services (DHHS) (see 45 CFR 46 as codified by HUD at 24 CFR 60), provide a copy of the approval of the research from an Institutional Review Board that is registered with DHHS (see Appendix A). Also, provide evidence that your organization has an institutional assurance that it will comply with the federal

policy for the protection of human subjects, that has been approved by the DHHS Office of Human Research Protections (i.e., provide the assurance number). ***[You should describe how you will ensure that your consent process will be understood by study participants and how you will ensure that you follow through with promises made to study participants (e.g., that they will be provided with the results of environmental sampling in a timely manner). Also, indicate how compliance with IRB requirements will be monitored during implementation of the study.]***

Grantees that must comply with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule should describe the procedures that will be followed to ensure compliance with these regulations.

2.0 MEASUREMENT/DATA ACQUISITION

2.1 EXPERIMENTAL DESIGN

In order to meet the objectives specified in the Project Management section above, the project experimental design is as follows. ***[Grantees and contractors should describe the experimental design or data collection design for the project and classify all measurements as critical (i.e., required to achieve project objectives) or non-critical (i.e., for informational or background purposes only). All relevant components of the experimental design should be described and rationalized, including the target group or population to be addressed; type and number of samples to be collected and analyzed; key parameters to be estimated; and date, location, and procedure for sample collection.]***

2.2 SAMPLING AND SURVEY METHODS

Procedures to be used for sample collection are described below. ***[For each biological/ environmental sample type, grantees and contractors should describe the procedures for collecting samples and identify the sampling methods and equipment. If the method is standard (e.g., an ASTM, ANSI, NIOSH, EPA, or CDC method), the organization name, standard number, title, date, and regulatory citation (as appropriate) are sufficient description. If a standard method will be modified slightly for this study, the standard method should be cited along with a description of the modification. If a non-standard method, or a significantly modified standard method, will be used, provide a brief description of the procedures to be used here (with references cited as appropriate), and details on the procedures to be used in the study in an appendix. The details for sampling procedures should include any implementation requirements; support facilities; determination of sample areas, volumes, or masses; materials and processes for selecting, preparing, and decontaminating sample containers; sample preservation requirements; and, if appropriate, disposal of decontamination by-products.]***

[For studies that include surveys, grantees and contractors should describe the procedures for administering the survey. This should include the survey sampling methodology and weighting factors. A copy of the survey instrument should be provided in the appendix. If computers (e.g., laptops, handheld PCs) will be used to collect the survey responses, then requirements for using the software should be described. Address the validity/reliability of the survey/assessment instrument. Grantees and contractors should use validated survey instruments or validate their instrument (i.e., determine that it is measuring what it is intended to measure and that the specific measures are reliable).]

[Additionally, grantees and contractors should describe specific performance requirements for the method, and address what to do when a failure in the sampling occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented.]

2.3 SAMPLE AND DATA HANDLING/CUSTODY

To ensure sample integrity throughout the collection and analysis process, the following sample handling and custody requirements will be followed. ***[Grantees and contractors should describe requirements and provisions for sample handling and custody in the field, laboratory, and transport, taking into account the nature of the samples, the maximum allowable sample holding times before extraction or analysis, and available shipping options and schedules. Grantees and contractors utilizing electronic equipment for collecting survey data should describe requirements for uploading the data and procedures (e.g., backups) for preventing any loss of data in the field. Specify titles of responsible personnel (listed in Table 1-1) for each component of sample handling and custody.]***

[Grantees and contractors also should include examples of sample labels, chain-of-custody forms, and sample custody logs in appendices to the QA Plan.]

2.4 ANALYTICAL METHODS

Analytical methods and equipment required for this project include ***[Grantees and contractors should identify the analytical methods and equipment required. If the method is standard (e.g., an ASTM, ANSI, NIOSH, EPA, or CDC method), the organization name, standard number, title, date, and regulatory citation (as appropriate) are sufficient description (if applicable, also state the particular options of the method that will be used). If a standard method will be modified slightly for this study, the standard method should be cited along with a description of the modification. If a non-standard method, or a significantly modified standard method, will be used, provide a brief description of the procedures to be used here (with references cited as appropriate), and details on the procedures to be used in the study in an appendix. The details also should include subsampling or extraction methods, laboratory decontamination procedures and materials (such as the case of hazardous samples), waste disposal requirements (if any), and specific performance requirements for the method.]***

[For non-standard methods, such as unusual sample matrices and situations, appropriate method performance study information is needed to confirm the performance of the method for the particular matrix. If previous performance studies are not available, they must be developed during the project and included as part of the project results.]

[Grantees and contractors should specify the laboratory turnaround time(s) needed, if important to the project schedule. Grantees and contractors also should address what to do when a failure in the analytical system occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented.]

2.5 QUALITY CONTROL

Quality control (QC) procedures to be implemented during this project are ***[Grantees and contractors should identify the required measurement QC checks for both the field and the laboratory; the frequency of analysis for each type of QC check; the spike materials, sources, and levels (if spike samples are to be used); whether replicates will be used; the statistical procedures to be used; the required control limits for each QC check (either explicitly or by reference); the corrective action required when control limits are exceeded; and how the effectiveness of the corrective action shall be determined and documented, using the specified measurement performance criteria from Section 1.5 above.]***

2.6 INSTRUMENT/EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE

[Grantees and contractors using laboratories that successfully participate in an appropriate lab QA program (e.g., NLLAP recognition, or EMLAP accreditation) need only cite that successful participation here. Alternatively, use the text/instructions below to describe the planned instrument/equipment testing, inspection, and maintenance procedures.]

To verify that all instruments and equipment are maintained in sound operating condition and are capable of operating at acceptable performance levels, the following inspections and acceptance testing procedures will be followed. ***[Grantees and contractors should describe the performance and documentation of inspections and acceptance testing of environmental sampling and measurement systems and their components.]***

[Grantees and contractors should describe methods for resolving deficiencies and when re-inspection will be performed.]

[Grantees and contractors should describe or reference how periodic preventive and corrective maintenance of measurement or test equipment will be performed. Equipment and/or systems requiring periodic maintenance shall be identified.]

2.7 INSTRUMENT/EQUIPMENT CALIBRATION AND FREQUENCY

[Grantees and contractors using laboratories that successfully participate in an appropriate lab QA program (e.g., NLLAP recognition, EMLAP accreditation) need only cite that successful participation here. Alternatively, use the text/instructions below to describe the planned instrument/equipment calibration and frequency procedures.]

Calibration procedures shall be performed on the following measurement equipment: ***[Grantees and contractors should identify all instruments, tools, gauges, and other sampling, measuring, and test equipment used for data collection activities affecting quality that must be controlled and, at specified periods, calibrated to maintain performance within specified limits.]*** Calibration procedures to be performed on the equipment to be used for instrumental analytical methods and other measurement methods include ***[Grantees and contractors should***

document the intended calibration procedure(s) that will be used for each instrument. If the calibration procedure is standard (e.g., an ASTM, ANSI, NIOSH, EPA, or CDC method), the organization name, standard number, title, date, and regulatory citation (as appropriate) are sufficient description. If a standard method will be modified slightly for this study, the standard method should be cited along with a description of the modification. Grantees and contractors also should describe how often each measurement instrument will be calibrated.]

[Grantees and contractors should identify the certified equipment and/or standards used for calibration. Grantees and contractors should describe or reference how calibration will be conducted using certified equipment and/or standards with known, valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, grantees and contractors should document the basis for the calibration. Grantees and contractors also should indicate how records of calibration shall be maintained and be traceable to the instrument.]

2.8 USE OF EXISTING DATA

Previously collected data, literature files, and other sources of outside information to be used in this project include: ***[Grantees and contractors should identify any types of data needed for project implementation or decision making that are obtained from such non-measurement sources as literature files and historical databases, and provide the documentary citations.]***

[Additionally, grantees and contractors should define the acceptance criteria for the use of such data in the project and discuss any limitations on the use of the data resulting from uncertainty in their quality. Examples of relevant acceptance criteria categories are representativeness, bias, and precision; project-specific quantitative criteria should be provided.]

2.9 DATA MANAGEMENT

Once the raw ("as collected") data have been collected, they will be handled according to the following data management procedures. ***[Grantees and contractors should describe the project data management scheme, tracing the path of the data from their generation in the field or laboratory to their final use and archiving. Grantees and contractors should describe or reference the standard record-keeping procedures, document control system, and approach to be used for data storage and retrieval on electronic media. For standard methods, if a method allows the user to select from various options, then the method citation should state exactly which options are being selected. Data entry procedures for ensuring the quality of entered data (e.g., double-data entry, range checks, etc.) should be discussed.]***

[Grantees and contractors should discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data reduction, data reporting, and

data entry to forms, reports, and databases. See above regarding standard procedures. Grantees and contractors should provide examples of any forms or checklists to be used for these purposes.]

[Grantees and contractors should identify and describe all data handling equipment and procedures to process, compile, and analyze the data, including any required computer hardware and software. See above regarding standard procedures. Grantees and contractors should address any specific performance requirements and describe the procedures that will be followed to demonstrate acceptability of the hardware/software configuration required.]

3.0 ASSESSMENT/OVERSIGHT

3.1 ASSESSMENTS AND RESPONSE ACTIONS

Evaluation and validation of this project will be ensured through the use of internal and external assessment activities. These assessment activities will ensure that all elements of the QA Plan have been correctly implemented, implementation of the QA Plan has generated data of adequate quality, and the necessary corrective actions have been implemented in a timely and effective manner. For this project, assessment activities to be performed include ***[Grantees and contractors should identify and describe each assessment activity to be performed in this project, as well as how frequently each activity will be performed. Possible assessment activities include, but are not limited to, field audits, management reviews, and laboratory audits. EPA's "Guidance on Technical Audits and Related Assessments" document (QA/G-7) can be consulted for information on conducting audits (www.epa.gov/quality/qs-docs/g7-final.pdf). This section should include a discussion of the information expected, the success criteria (e.g., goals, performance objectives), and the responsible person(s) who will conduct the assessment for each assessment proposed.]***

The schedule for audit activities is ***[Grantees and contractors should list the approximate schedule of activities.]*** Assessment personnel will include ***[Grantees and contractors should identify the potential organizations and participants who will perform the assessments and to whom they will report their findings within the organizational structure presented in Figure 1-1.]***

The individual responsible for ensuring that corrective action is taken is ***[Grantees and contractors should identify who is responsible for overseeing the response action to non-conforming conditions.]*** The protocol for effectively addressing corrective actions is ***[Grantees and contractors should discuss how response actions to non-conforming conditions shall be addressed and describe how response actions shall be verified and documented.]***

3.2 REPORTS TO HUD

Written reports covering the progress made and the results of this study will be delivered to the HUD GTR on a regular basis. The schedule for these reports is provided in Table 3-1.

Table 3-1. Schedule of Reports for *[Insert Project Name]*

Report	Due Date
QA Plan	
Quarterly Progress Reports	
Tenant/Owner Notifications	
Final report/manuscript (draft)	
Final report/manuscript (final)	
Data Report	

As shown in the table, various types of reports will be written. Descriptions of these reports are as follows.

- QA Plan – this document

- Quarterly Progress Report – a brief report that updates HUD on the work that has been performed over the last quarter. Items such as number of samples collected and analyzed, number of surveys completed, problems encountered in the field or laboratory, and comparisons with schedule and budget milestones will be included.

- Tenant/Owner Notifications – a document that reports the analytical results to the tenant and/or owner of the residential unit where sampling or visual inspections occurred (may not be applicable to all grants).

- Final Report – a document that provides a complete description of the project, including the results of evaluation activities and overall conclusions with respect to original objectives and hypotheses.

- Journal Manuscript – a manuscript that documents the work performed, results obtained, and conclusions reached for the study. The manuscript will be suitable for publication in a scientific, peer-reviewed journal ***[add text specifying the names of likely journals]***. Based on discussions with the GTR, it may be agreed that one or more manuscripts may be submitted as a final report.

- Data Report – a fully documented electronic dataset of the data collected during the study. A CD ***[specify different media if necessary]*** containing the study data will be produced that is suitable for distribution to the public. ***[Specify data format (e.g., ASCII comma-delimited text file, Excel spreadsheet, Access database, SAS export data file, etc.) for each component of the dataset.]*** In addition to the data files, an electronic data dictionary that describes the contents of each data field (including the data format) will be included on the CD.

[Reports listed above are routinely expected to be provided. Grantees and contractors should consult with their GTR for final guidance on what specific documents are required under their grant and when those documents must be submitted.]

4.0 DATA VERIFICATION AND USABILITY

4.1 DATA REVIEW AND VERIFICATION

In order to determine if data collected during the project meet the stated data quality objectives (Section 1.5), the Study QA Manager will subject all data to a verification process. Data will be reviewed using the criteria specified below, and any data that fail to meet any of the criteria will be investigated as described in Section 4.2. If data errors cannot be corrected (i.e., errors other than calculation errors, data entry errors, transcription errors, etc.), those data will be excluded from final analyses.

[Grantees and contractors should state here the criteria used to review and validate data.]

4.2 VERIFICATION METHODS

Data verification will be performed to ensure that the criteria specified in Section 4.1 have been met. Methods for verifying the compliance, correctness, consistency, and completeness of the data are described below.

[Each verification element is defined below. In place of each definition, supply the appropriate details on how the verification will occur, as applicable to this study. EPA's "Guidance on Environmental Data Verification and Validation" document (QA/G-8) can be referenced for additional details about these verification elements (www.epa.gov/quality/qs-docs/g8-final.pdf).

Compliance - ***verifies that the values of individual data points meet the criteria specified in the QA Plan and that data collection adheres to standard operating procedures (SOPs).***

Correctness - ***evaluates whether data collection protocols were followed and basic operations and calculations were performed correctly.***

Consistency - ***evaluates the comparability of data reported over multiple places and collection sites, determining whether collection procedures were followed in the same manner.***

Completeness - ***obtains all required data and reports deficiencies.***

Grantees and contractors should provide examples of any project-specific calculations and any forms or checklists to be used in performing the verification.]

[The following text may not be applicable to every grantee or contractor. Grantees and contractors should add to, delete from, and expand on the discussion that is provided.]

Visual and electronic comparisons of sample data against raw data collection forms,

review of QC-charts and other data plots, and outlier checks will be performed to identify possibly erroneous data. When data problems are found, the Study QA Manager will notify the responsible person for the data (field coordinator, data management coordinator, laboratory director, etc.). This individual will attempt to resolve the data problem. Possible solutions include correcting a mistake in a spreadsheet formula, correcting a calibration curve, and correcting data entry errors due to sloppy handwriting on data collection forms. Corrected data will be re-submitted to the Study QA Manager for verification again.

Data that are confirmed to be in error but cannot be corrected (e.g., sample was contaminated in laboratory) will be removed from the study database and replaced with a flag indicating the specific problem. Data that appear suspicious but have no reason for which to invalidate them will be reported in the database accompanied by a flag that indicates their possible outlier status. Analysts and users of the data will need to consider how to include these data points in their analyses.

4.3 RECONCILIATION WITH USER OBJECTIVES

Reconciliation with the data quality objectives specified in Section 1.5 will be performed once all data problems have been resolved. ***[Grantees and contractors should provide details on how this reconciliation will occur. Methods to analyze the data and determine possible anomalies or departures from assumptions established in the planning phase of data collection should be outlined. A discussion of how issues will be resolved and how limitations on the use of the data also should be provided.]***

[Grantees and contractors should state under what circumstances re-sampling will be performed for cases where the collected data do not meet the stated data quality objectives.]

APPENDICES