Quality Assurance Plan
for HUD Healthy Homes Demonstration Grantees

TEMPLATE

VERSION 1.1

November 2005

PREFACE

HUD Healthy Homes Initiative (HHI) Demonstration Studies grantees are required to develop a Quality Assurance Plan (QA Plan), in accordance with HUD and OMB Information Quality Guidelines (IQG), before collecting any data for their grant (a more complete QA Plan is required of Technical Studies grantees). The attached template has been written to assist grantees 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 should modify the text as appropriate to fit the needs of their organization and project. The specific writing responsibilities of the grantee 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 and analysis 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.

This template is a simplified version of the template created for the QA Plan required of Technical Studies grantees, which 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.

[Insert Title of Specific Project]

[Insert Organization Name and Address]

[Insert Grant Number]

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

_____

Project Director

Date

[Insert Name]

Reviewed and Approved for HUD Office of Healthy Homes and Lead Hazard Control:

_____

Date

[Insert Name]

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1.0 PROJECT MANAGEMENT

1.1 PROJECT ORGANIZATION

As project director, ***[insert name of project director]*** will have overall responsibility for this project. The individuals who will assist ***[him/her]*** are listed below, followed by a brief description of their responsibilities. Figure 1-1 displays the organizational relationships among these individuals.

[Grantees should include an organizational chart with contact information(telephone and email address) under each individual included in the chart. Grantees need to identify all individuals or organizations participating in the project and briefly describe their specific roles and responsibilities. The organizational chart should show relationships and lines of responsibility and communication among project participants, data users outside the organization generating data, and any subcontractors or subgrantees involved in collecting or processing data.]

Figure 1-1. Organizational Structure for *[Insert Organization Name, Grant Name, Grant Number]*

1.2 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 project 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.]

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 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
Project Design, Develop QA Plan	(----)								
IRB Approval		(-------)							
Enrollment of Participants			(----------)						
Sample Collection			(----------)						
Laboratory Analysis			(----------)						
Database Management		(----------)							
Statistical Analysis						(----------)			
Report Writing								(---------)	

Figure 1-2. Schedule of Accomplishments and Milestones

1.3 DOCUMENTATION AND RECORDS

The following documentation will be maintained in the data records from this study. ***[Grantees 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), and data handling records.]*** These records will be reported in the following formats: ***[Grantees should state the desired reporting format for hard copy and electronic forms.]***

[Grantees 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.]

1.4 HUMAN SUBJECTS RESEARCH

[This section is applicable only to those projects involving human subject research as defined by the Department of Health and Human Services (DHHS) (see 45 CFR 46 as codified by HUD at 24 CFR 60). Grantees should be aware that "human subject research" is broadly defined by these regulations.]

A copy of the Institutional Review Board (IRB) approval for this study is provided in Appendix A. The assurance number that indicates that the Department of Health and Human Service's Office of Human Research protection has approved ***[insert organization name]***'s institutional procedures to comply with the federal policy for the protection of human subjects is

[insert assurance number].

[Grantees should describe how assurances will be made that their consent process will be understood by study participants and how they will ensure that they follow through with promises made to study participants (e.g., that participants will be provided with the results of environmental sampling in a timely manner). Also, a discussion of how compliance with IRB requirements will be monitored during implementation of the study should be provided.]

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 SAMPLING AND SURVEY METHODS

[For projects that involve sample collection, Grantees should describe the procedures for collecting samples and identify the sampling methods and equipment (details need to be provided for each biological/environmental sample type). If the method is standard (e.g., an ASTM, or EPA method), the organization name, standard number, title, and date) 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 projects that include surveys, Grantees should describe the procedures for administering the survey. 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. Grantees should use validated survey instruments or validate their instrument, if possible (i.e., determine that it is measuring what it is intended to measure and that the specific measures are reliable).]

2.2 SAMPLE AND DATA HANDLING/CUSTODY

To ensure sample integrity throughout the collection and analysis process, the following sample handling and custody requirements will be implemented. ***[Grantees 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 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.]

2.3 ANALYTICAL METHODS

Samples collected for this study will be sent to ***[insert laboratory name]*** for analysis. ***[Insert laboratory name]*** is accredited by ***[insert appropriate laboratory accreditations]***. ***[Grantees should specify the laboratory turnaround time(s) needed, if important to the project schedule.]***

[Grantees should provide a short discussion about the specific analytical methods to be used by the laboratory(you will need to ask your laboratory to provide this). If the method is standard (e.g., an ASTM EPA, or CDC method), the organization name, standard number, title, and date 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, if applicable.]

2.4 QUALITY CONTROL

Quality control (QC) procedures to be implemented during this project are described below. ***[Grantees 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. Grantees can obtain most of this information from their laboratory.]***

2.5 DATA MANAGEMENT

Once the raw ("as collected") data have been collected, they will be handled according to the following data management procedures. ***[Grantees 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 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, a method citation should be provided that states 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 should discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data entry, data reduction, and data reporting. See above regarding standard procedures. Grantees should provide examples of any forms or checklists to be used for these purposes.]

[Grantees 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.]

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 any necessary corrective actions have been implemented in a timely and effective manner. For this project, assessment activities to be performed include ***[Grantees 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.***

The schedule for audit activities is ***[Grantees should list the approximate schedule of activities.]*** Assessment personnel will include ***[Grantees 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 should identify who is responsible for overseeing the response action to non-conforming conditions.]***

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	
Final report or Manuscript (draft)	
Final report or Manuscript (final)	

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 (if applicable) – 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]***.
[Reports listed above are routinely expected to be provided. Grantees 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 minimum quality objectives, the Project Director will ensure that all data are subjected to a two-step verification process. The first step (done at the QA Plan writing stage) is to establish the criteria by which the data will be reviewed. See below for the specific criteria that will be used for this project. The second step will be to review the data and document the results. 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 should state here the criteria used to review and validate data. Some examples of how the criteria may be stated are provided below. These are only examples, and grantees should add to, delete from, and modify them as appropriate.

For environmental data collected in the field, data are required to meet criteria such as:

- ***Samples were collected from locations specified in sampling protocol.***
- ***Analytical results were obtained for at least 95% of the samples collected.***
- ***Analytical results for QC spike samples sent with collected samples are within ±20% of***

their "true" value.

- ***Analytical results for blanks sent with collected samples are less than the detection limit.***

For survey data, data are required to meet criteria such as:

- ***Surveys were completed by intended respondents (e.g., tenants, property owners, etc.).***
- ***At least 95% of the surveys were returned with at least 90% of the appropriate questions answered.***

For all types of data, verifications will be done such as:

- ***Trace 10% of the data from their raw form through their final form in the database, checking for accuracy of transcriptions, calculations, etc.***

Grantees should develop a very simple tracking sheet that provides a format for documenting the data review that shows such things as the date the data were checked, the type of criteria evaluated, the results, and the resolution of errors found.]

APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL
(To be added if applicable)

APPENDIX B

SAMPLING PROTOCOLS
(To be added if applicable)

APPENDIX C

ANALYTICAL METHODS
(To be added if applicable)

APPENDIX D

SAMPLE LABELS
(To be added if applicable)

APPENDIX E

SAMPLE CUSTODY FORMS
(To be added if applicable)

APPENDIX F

SURVEY INSTRUMENTS
(To be added if applicable)