# Quality Assurance Project Plan (QAPP) Template: State Environmental Results Programs (ERPs) Funded by EPA State Innovation Grants (SIGs)

**[REMOVE THESE TWO PAGES BEFORE SUBMITTING.]**

**PURPOSE:** This DRAFT template is intended to help improve the quality assurance (QA) capabilities and understanding of State Innovation Grant (SIG) recipients that are undertaking Environmental Results Programs (ERPs)—initiatives that use a combination of technical assistance, self-certification, inspections, and statistically based performance measures to improve environmental performance in small-business sectors. This template is expected to improve the rigor and consistency of Quality Assurance Project Plans (QAPPs) submitted to EPA and thereby improve both SIG project design and the quality and usability of the data and analysis resulting from SIG projects. The design of this template is also expected to streamline the QAPP submission and review process, potentially leading to earlier project implementation.

**BACKGROUND:** This QAPP template was prepared based upon review of EPA guidance on QAPPs, and past SIG proposals and QAPPs. In its structure, this template adheres closely to the recommended QAPP review sheet. This structure will help ensure broad applicability and a streamlined review process for EPA Regions and Headquarters. In content, the template provides "boilerplate" language that is likely to be useful for many SIG recipients. However, every project is unique, and you should tailor the text to suit your needs.

Please note that this template is not an official EPA document, has not undergone review by all relevant EPA QA specialists, and may be modified in the future based upon such review.

**ASSUMPTIONS:** This template was prepared to meet the needs of a “typical” state ERP. It assumes that all major components of a traditional ERP will be employed. If your initiative is a modified ERP, you may need additional guidance beyond that which is provided in the template.

**USAGE:** Text that is enclosed in square brackets and highlighted in yellow is meant to be changed by the user. (You might want to change other text as well, depending on the nature of your initiative.) Guidance/advice for particular sections is enclosed in Microsoft Word comments. If you are using a version of Microsoft Word from 2003 or later, set View to “Print Layout” and comments will appear in the right-hand margin. If you are using an earlier version of Word, you will see the comments when the mouse passes over particular flagged passages or in a window at the bottom of the screen. With these earlier versions of Word (or with other word processors), you might find it easier to view a hardcopy or electronic copy of the Adobe PDF version of the template, also available from EPA's National Center for Environmental Innovation. You may find it helpful to view the hardcopy while editing the electronic text in your word processor.

**Hyperlink usage.** Depending on your version of Microsoft Word and your user settings, you might be able to access hyperlinked documents and web pages by simultaneously pressing “Ctrl” and right-clicking with your mouse, or you might need to copy and paste the URL directly into your browser.

**PRE-SUBMISSION CLEANUP:** Before submitting your customized QAPP to EPA, it is recommended that you remove yellow highlighting, make sure all bracketed text has been replaced with your own text, and update the table of contents and lists of tables and/or figures. You may also wish to remove Microsoft Word comments that you and other readers are not likely to need in the future. Instructions on how to carry out these tasks are included below. Note that the instructions were developed based on commands and functions available in Microsoft Word 2003. If you are using a different version of

Microsoft Word, you may find that the commands in your version are slightly different than the commands described here.

**Removing highlighting.** To remove all highlighting, first select all text in the document by choosing "Edit/Select All" from the menu. Click on the arrow next to  (the highlighting icon) on the toolbar and then select "None" from the color options available in the pop-up window. (If you do not see  on the toolbar, make sure that the formatting toolbar is visible by right-clicking anywhere in the toolbar area. If "Formatting" is not selected, click on it.) Highlighting in the header must be taken out separately. Double-click on the header, select the highlighted text, and proceed as above.

**Removing bracketed text.** To make sure that all bracketed text has been replaced, use the search function in Microsoft Word, found under "Edit/Find" on the menu. Type "[" or "]" in the box next to "Find What" and then click "Find Next." Replace any brackets you find and repeat the process until a pop-up window appears, indicating that no occurrences of the search term were found. Be sure to check the header for bracketed text as well.

**Updating table of contents, etc.** To update a table of contents or other reference table (e.g., list of figures), first select the reference table by clicking anywhere on the table. With the table selected, press the F9 key. Note that when you update a reference table, any text or formatting that you have added to the table is lost. Note also that the table of contents and other reference tables are generated based upon the formatting styles used for the headings for different sections and subsections of this template.

**Removing comments.** To delete all comments from the document, click on the arrow next to  ("Reject Change/Delete Comment") and then click "Delete All Comments in Document." (If you do not see  on the toolbar, make sure that the reviewing toolbar is visible by right-clicking anywhere in the toolbar area. If "Reviewing" is not selected, click on it.) To delete an individual comment, right-click on the comment and click "Delete Comment."

**AMENDING THE QAPP:** This template assumes that the QAPP submitted with your proposal/workplan will not have all of the details you will need before you begin data collection. It assumes that you will amend your QAPP in the future after completion of key planning steps, but before data collection begins.

**VERSION NOTES:** this draft QAPP template was prepared initially in June 2004. In September 2005, this template instructions section was added, along with some minor formatting improvements and a suggestion for users to provide an abstract. The substance of this template remains unchanged from the June 2004 version.

**[Insert state agency name here]**

**[Insert project title here]**

**Quality Assurance Project Plan**

**[Insert agency name and address here]**

**[Insert full contact information for project manager]**

**Abstract:** This document details a quality assurance plan to guide the successful implementation of [name of project]. [Provide a very brief summary of the project, to orient the reader. Two to three sentences should be sufficient. A more detailed description of the project will be given in A6.]

# A PROJECT MANAGEMENT

## A1. Approval Sheet

_____ _____

[Insert name of project manager]
[Insert agency name]
Title

Date

_____ _____

[Insert QA Officer name]
[Insert agency name]
Quality Assurance Officer Bureau of Water

Date

_____ _____

X [Insert other partner] X
XXXXXXXXXXXXXXX
Title

Date

_____ _____

XXXXXXXXXXXXXXX
X [Insert other partner] X
Title

Date

## A2. Table of Contents

[be sure to update table of contents & header]



### List of Tables



### List of Tables

## A3. Distribution List

Each person listed on the approval sheet and each person listed under Project/Task Organization will receive a copy of this Quality Assurance Project Plan (QAPP). Individuals taking part in the project may request additional copies of the QAPP from personnel listed under Section A4.

This document has been prepared according to the United States Environmental Protection Agency publication *EPA Requirements for Quality Assurance Project Plans* dated March 2001 (QA/R-5).

## A4. Project/Task Organization

Personnel involved in project implementation are listed in Table 1, and shown as an organization chart in Figure 1.

**Table 1: Project Implementation Personnel**

| Individual | Role in Project | Organizational Affiliation |
|---|---|---|
| | Project Manager | |
| | QA Manager/Officer | |
| | | |
| | | |
| | | |
| | | |
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| | | |
| | | |

The [Insert agency name] Project Manager will be responsible for the following activities:

- Conduct outreach with regulated industry and internal/external stakeholders
- [Insert other tasks here]
- Maintain official, approved QAPP
- Develop amended QAPP
- Issue quarterly and annual reports to U.S. EPA

[Contractor, if applicable; if contractor name not known yet, identify as contractor to be determined (TBD)] will be responsible for the following activities:

- [Insert contractor tasks here, including tasks specifically related to QA/QC]
-

[Partner, if applicable; if partner name not known yet, identify as partner to be determined (TBD)] will be responsible for the following activities:

- [Insert partner tasks here, including tasks specifically related to QA/QC; e.g., a community group assisting in the identification of the facility universe]

The participating facilities will be responsible for submitting self-certification materials and, if applicable, returning to compliance.

**Figure 1: Project Organizational Chart**

[insert chart]

## A5. Problem Definition/Background

### Rationale for initiating the project

[Insert text related to the problem this project is trying to solve]

### Objectives of the project

[Insert text explaining anticipated outcomes and decisions/outcomes (both regulatory and non-regulatory) to be taken based upon the data collected.]

### Regulatory information, applicable criteria and action limits

[Identify regulatory information, applicable criteria, action limits, etc. that are necessary to the project.]

## A6. Project/Task Description

### Project overview

This project will allow [Insert agency name] to explore whether an approach modeled upon the Environmental Results Program (ERP) can help achieve these goals, while improving regulatory cost-effectiveness. The Environmental Results Program (ERP) is an innovative approach to solving high-priority environmental problems in industry sectors largely comprised of small businesses. The ERP concept combines technical assistance, self-certification, inspections, and statistically based performance measurement in order to reduce environmental impacts of business.

The promise of ERP is that it will cost-effectively reduce environmental impacts of small businesses that may present a substantial cumulative environmental risk. Businesses targeted so far by ERP include gas stations, auto salvage yards, auto body and mechanical repair shops, dry cleaners, and printers. ERP can help environmental agencies identify previously unknown facilities, measure performance, increase regulatory efficiency, and help improve overall

environmental performance. ERP is in part designed to help facilities that want to comply but don't understand their requirements, and evidence suggests that ERP can motivate firms to comprehensively review their environmental performance and take needed action to come into compliance and adopt best practices.

## Project summary and work schedule

This project's major tasks and timeline are outlined in the table below.

**Table 2: Schedule of Major Project Tasks**

| Task Name | Task Description | Start Date | End Date |
|---|---|---|---|
| Outreach | Outreach to internal and external stakeholders (including targeted facilities) about the project. | | |
| Goals identification | Finalize the goals of this project, upon which metrics will be based | | |
| Measures identification | Finalization of metrics to be tracked by this project. | | |
| Facility identification | Determine the exact characteristics of facilities to be included in this project, and compile a list of facilities from reliable sources. [In some cases: work with community groups, industry associations, etc. to actively identify targeted facilities.] | | |
| Statistical methodology | Development of a statistical methodology to drive performance measurement and analytical tasks. | | |
| Data input & management | Development and implementation of an approach to cost-effectively inputting and managing ERP data, including primary and secondary data. Primary data consists of data from inspection reports and facility forms (including self-certification forms). Secondary data sources include lists of facilities from regulatory and private-sector databases. | | |
| QAPP finalization & approval | Finalize QAPP based upon results of the measures identification, statistical methodology, and data management tasks. Primary data collection will not occur before relevant parts of the QAPP are finalized and approved by EPA. | | |

**Table 2: Schedule of Major Project Tasks**

| Task Name | Task Description | Start Date | End Date |
|---|---|---|---|
| Baseline inspections (establishing a performance measures baseline) | Inspections at facilities to establish a baseline for performance measures. Facilities selected at random from the entire targeted population, based upon sample design from statistical methodology. | | |
| Baseline analysis | Analysis of inspection data to establish a baseline for the project's performance measures. | | |
| Facility assistance | Delivery of compliance/technical assistance to facilities, which is expected to take the form of workbooks, fact sheets and/or workshops. | | |
| Self-certification | Implementation of a [voluntary/mandatory] facility self-certification approach. Self-certification refers to the submission of a legally binding record of a facility's compliance and beyond-compliance practices. | | |
| Analysis of self-certification results | Analysis of self-certification data, with primary purpose of identifying opportunities for selective follow-up (next step). | | |
| Selective follow-up | Selective follow-up with self-certifying facilities, based upon analysis of self-certification data. Selective follow-up may include phone calls, inspections and enforcement. Selective follow-up is not typically based upon a random sample. | | |
| Post-certification inspections | Inspections at facilities to establish whether sector performance measures (and other measures) have changed since the baseline. Inspection data also used to cross-check self-certification data at inspected facilities. Facilities selected at random from the entire universe of facilities, based upon sample design from statistical methodology. | | |
| Data analysis | Analysis of baseline, self-certification, and post-certification data to understand change in facility performance and overall outcomes of interest. Assessment of project efficiency. | | |
| Reporting to EPA | Reporting shall include quarterly, annual and final reports. | | |
| [Other??] | | | |

### Geographic focus

[ID locations of facilities to be studied]

### Resource and time constraints

[Insert, to best of your knowledge]

## A7. Quality Objectives and Criteria

### Detailed performance measures

This project is primarily interested in the following list of likely performance measures. Note that one of the tasks of this project involves revisiting and reaffirming/revising these draft performance measures. The final list will be submitted in a QAPP amendment. [Insert draft list of performance measures this project will track and analyze.]

### Quality objectives

Quality objectives for these performance measures will be developed as part of the Measures Identification and Statistical Methodology tasks. Specific quality objectives for these measures as a group (and, if necessary, individually) will be provided in the anticipated amendment to the QAPP.

The amendment to the QAPP will ensure that the quality objectives for these performance measures are appropriate for the regulatory and non-regulatory decisions to be made based upon those measures. This determination will take into account both the best practices for similar projects and the resources available for this project. In part, the Project Manager will rely upon EPA's *Generic Guide to Statistical Aspects of Developing an Environmental Results Program* (2003) for advice in making decisions related to the optimizing the following aspects of data quality for this project:

- Precision
- Bias
- Representativeness
- Completeness
- Comparability
- Sensitivity (if applicable)

## A8. Special Training/Certification

The [Insert agency name] and [if applicable, insert contractor/partner name] will develop and deliver mandatory and voluntary training sessions to key parties to ensure quality data collection, to the extent practicable.

Mandatory intensive in-person training sessions will be delivered to the following individuals to ensure quality data collection:

- inspectors who will be collecting baseline and post-certification data
- data-entry personnel who will be processing data from inspections and self-certification responses
- QA/QC personnel (if any additional training is needed to familiarize them with the project)
- Individuals who will be compiling the database containing the universe of facilities

Each session will cover proper data collection and QA procedures. Training will be augmented by debriefing personnel shortly after their tasks have begun, to correct and clarify appropriate practices.

Voluntary intensive in-person training sessions will be offered to the self-certifying facilities. Facilities will also be provided with clear written instructions on how to prepare and submit data, and they will be able to call a phone number to ask anonymous questions if they wish.

The Project Manager is responsible for ensuring that all personnel involved with data generation (including state personnel, contractors, and partners) have the necessary QA training to successfully complete their tasks and functions. The Project Manager will document attendance at all training sessions. Attendance records for voluntary trainings may not include names, given privacy/confidentiality concerns.

The Project Manager is also responsible for ensuring the self-certification materials sent to facilities clearly document how facilities should properly prepare and submit their data.

## A9. Documents and Records

### Report format/information

The format for all data reporting packages will be consistent with the requirements and procedures used for data validation and data assessment described in this QAPP.

### Document/record control

The recording media for the project will be both paper and electronic. The project will implement proper document control procedures for both, consistent with [Insert agency name here]'s Quality Management Plan. For instance, hand-recorded data records will be taken with indelible ink, and changes to such data records will be made by drawing a single line through the error with an initial by the responsible person. The Project Manager will have ultimate responsibility for any and all changes to records and documents. Similar controls will be put in place for electronic records.

The [Insert agency name] Quality Assurance Officer shall retain all updated versions of the QAPP and be responsible for distribution of the current version of the QAPP. The [Insert agency name] Quality Assurance Officer and the [Insert agency name] Project Manager will approve annual updates. The Project Manager shall retain copies of all management reports, memoranda, and all correspondence between the [Insert agency name] and all project personnel identified in A4.

### Other records/documents

Other records and documents that will produced in conjunction with this project include:

- Inspection checklists and reports
- Self-certification forms
- Return-to-compliance forms
- Non-applicability forms
- Enforcement documentation
- Facility outreach materials, including workbook, fact sheets, brochures, etc.
- Amended QAPP
- Readiness reviews (see below)
- Data handling reports
- Quarterly and annual progress reports to EPA
- Project final report (to include discussion of QA issues encountered, and how they were resolved)

### Storage of project information

[where, and for how long]

### Backup of electronic files

[Insert backup plans for documents & records.]

## B DATA GENERATION AND ACQUISITION

### B1. Sampling Process Design (Experimental Design)

A key task in this project will be to develop a sound statistical methodology for collecting and analyzing facility data, in order to draw inferences related to the selected performance measures. The major quality objective will be to collect representative data that truly reflect the conditions of the universe of facilities that this ERP focuses upon . Facility data is of two types: (1) inspection data, which will be collected by trained [Insert agency name] inspectors from randomly sampled facilities, and (2) self-certification data[1], which will be collected from facilities through a mail survey process. Facilities will be required to respond, so this step is similar to a census. While the precise methods are not know at this point, they are expected to be

[1] Includes data from self-certification forms, return-to-compliance forms, and non-applicability forms. [the latter may not be relevant for voluntary programs]

built upon the advice given in EPA's *Generic Guide to Statistical Aspects of Developing and Environmental Results Program* (2003).

This section of the QAPP will be amended upon completion of the project-specific statistical methodology.

## B2. Sampling Methods

As described above, the primary data collected and used by this ERP will come from a survey data collection process. This section of the QAPP will be amended upon completion of the project-specific statistical methodology, which will detail the statistical sampling methods to be used. As mentioned elsewhere, that methodology will be prepared consistent with the principles identified in the EPA's *Generic Guide to Statistical Aspects of Developing an Environmental Results Program* (2003).

### Preparation of data collection instruments

All data collection instruments will be subject to multiple rounds of review by relevant internal and external stakeholders to help assure the collection of high-quality and representative data. Data collection instruments will be prepared in accordance with the guidance on data collection instruments provided in EPA's *Generic Guide to Statistical Aspects of Developing an Environmental Results Program* (2003). Specifically, preparation will follow the checklist for data collection instruments provided in an appendix of that guide.

## B3. Sample Handling and Custody

Upon completion of paper checklists, inspectors will sign the checklists. Inspectors will enter data from paper checklists into the electronic database. Facilities will mail signed forms into [Insert agency name], where data-entry staff will input data into the electronic database.

Chain of custody is not relevant to this project.

### Data entry QA procedures

Procedures for entering hand-written data into the database will follow standard quality assurance procedures (e.g., 100% verification using independent double key entry), consistent with [Insert agency name]'s Quality Management Plan. Detailed quality assurance procedures for data entry and acceptance will be prepared during the development and implementation of a data management strategy. The final QAPP will reflect the strategy.

## B4. Analytical Methods

This project will follow well-recognized statistical analytical methods for survey samples. This section will be amended upon completion of the detailed statistical methodology. No physical tests or chemical analyses are anticipated for this project.

## B5. Quality Control

This project will undertake the following specific steps to measure/estimate the effect of data errors, consistent with [Insert agency name]'s Quality Management Plan.

### Crosschecking data

Primary data collection forms will be designed in such a way to allow internal crosschecking of data by comparing answers of different questions to each other, and such crosschecking will be automatic for electronically entered data. Further, post-certification inspections will offer the opportunity to compare inspection results with self-certification results, if the facilities sampled have submitted self-certification forms.

### Data anomalies

Procedures for handling data anomalies (such as outliers and missing data) will be handled based on guidance prepared in the project-specific statistical methodology.

### Quality control statistics

The quality control statistics to be used in this project are described in more detail in section D3.

## B6. Instrument/Equipment Testing, Inspection and Maintenance

This section is not relevant to this project. The project will not involve such scientific instruments and equipment.

## B7. Instrument/Equipment Calibration and Frequency

This section is not relevant to this project. The project will not involve such scientific instruments and equipment.

## B8. Inspection/Acceptance for Supplies and Consumables

This section is not relevant to this project. The project will not involve such supplies and consumables.

## B9. Non-Direct Measurements (I.e., Secondary Data)

This project will rely upon secondary data to identify the facilities in the target population. [Identify any other anticipated uses of secondary data]

**Table 3: Non-Direct Measurements (i.e., Secondary Data)**

| Data Sources | Intended Use | Rationale for Use | Acceptance Criteria |
|---|---|---|---|
| [Insert agency name] database of facilities | Identifying the target population, for the sample | Commonly accepted source of facility list | All records will be accepted unless sample response indicates facility should not be part of target population. [Insert agency name] will crosscheck any facility that self-identifies as non-applicable to this project. |
| [insert other known data sources, with similar language for each column] | | | |
| | | | |
| | | | |
| | | | |

### Key resources/support facilities needed

[Insert agency name] will require access to the data sources mentioned above, and this information will be managed within the database created/utilized for the overall project. [Insert agency name] does not anticipate any obstacles to this approach.

### Determining limits to validity and operating conditions

Database containing the list of targeted facilities will be designed such that the original source for all facility data is marked, and procedures will be in place such that only the Project Manager can officially remove a facility entry from the target population. In such cases, facility entry will not be deleted from the database but will be marked as nonapplicable, and corrective data will be provided in fields parallel to the original data.

[Add more information about this topic if using different kinds of secondary data]

### B10. Data Management

As part of this project, [Insert agency name] [if applicable, also mention contractor involvement] will develop a data management strategy, and amend the QAPP based upon the strategy. The Project Manager is responsible for ensuring that that strategy is developed and that the QAPP is amended to reflect that strategy. The strategy will be consistent with the existing [Insert agency name]'s Quality Management Plan. Once amended, this QAPP section on data management will provide information on the following issues:

- Data management scheme, from field to final use and storage
- Standard recordkeeping and tracking practices, and document control system (citing relevant agency documentation)
- Data handling equipment/procedures that will be used to process, compile, analyze, and transmit data reliably and accurately
- Individuals responsible for elements of the data management scheme
- Process for data archival and retrieval

## C ASSESSMENT/OVERSIGHT

### C1. Assessment and Response Actions

The Quality Assurance Officer will conduct a Readiness Review immediately prior to the five major data collection tasks: identifying targeted facilities, baseline inspections, self-certification, targeted follow-up, and post-certification inspections.. The QA Officer will report findings to the Project Manager, who will take corrective action (if any is necessary) before the data collection task begins. Further, the Project Manager and QA Officer will thoroughly debrief project implementation staff a short time after beginning their respective implementation tasks, to identify emerging/unanticipated problems and take corrective action, if necessary.

### C2. Reports to Management

Three kinds of reports will be prepared: readiness reviews (described above), regular quarterly and annual progress reports, and project final report. Progress reports will note the status of project activities and identify whether any QA problems were encountered (and, if so, how they were handled). Project final report will analyze and interpret data, present observations, draw conclusions, identify data gaps, and describe any limitations in the way the data should be used.

**Table 4: Project QA Status Reports**

| Type of Report | Frequency | Preparer | Recipients |
|---|---|---|---|
| Amended QAPP | Once, before primary data collection begins | [Insert agency name] Project Manager | All recipients of original QAPP |
| Readiness Review | Before each major data collection task | [Insert agency name] QA Officer | [Insert agency name] Project Manager, [project manager supervisor?] |
| Progress Report | Quarterly | [Insert agency name] | U.S. EPA Project Officer (Copying US EPA OPEI) |
| Progress Report | Annually | [Insert agency name] | U.S. EPA Project Officer (Copying US EPA OPEI), stakeholders |
| Final Project Report | Once | [Insert agency name] | U.S. EPA Project Officer (Copying US EPA OPEI), stakeholders |

## D DATA REVIEW AND EVALUATION

### D1. Data Review, Verification and Validation

This QAPP shall govern the operation of the project at all times. Each responsible party listed in Section A4 shall adhere to the procedural requirements of the QAPP and ensure that subordinate personnel do likewise.

This QAPP shall be reviewed at least annually to ensure that the project will achieve all intended purposes. All the responsible persons listed in Section A4 shall participate in the review of the QAPP. The Project Manager and the Quality Assurance Officer are responsible for determining that data are of adequate quality to support this project. The project will be modified as directed by the Project Manager. The Project Manager shall be responsible for the implementation of changes to the project and shall document the effective date of all changes made.

It is expected that from time to time ongoing and perhaps unexpected changes will need to be made to the project. The Project Manager shall authorize all changes or deviations in the operation of the project. Any significant changes will be noted in the next report to EPA, and shall be considered an amendment to the QAPP. All verification and validation methods will be noted in the analysis provided in the final project report.

## D2. Verification and Validation Methods

To confirm that QA/QC steps have been handled in accordance with the QAPP, a readiness review will be conducted before key data collection/analysis steps, and data handling reports will be prepared after each step. These reviews and reports will be consistent with [Insert agency name]'s Quality Management Plan. Standard statistical tests (described below in Section D3) will be used to determine the extent to which inferences can be drawn from the sample data.

## D3. Evaluating Data in Terms of User Needs

This section will be written and finalized after completion of the project-specific statistical methodology, which will be developed consistent with [Insert agency name]'s Quality Management Plan and EPA's *Generic Guide to Statistical Aspects of Developing an Environmental Results Program* (2003). This section will present the following information:

### Meeting and reporting needs of your project

This section shall contain a description of how the results of the study will be analyzed and evaluated to determine whether the needs of the project were met and then reported.

### Mathematical and statistical formulae

This section shall contain details of formulae that will be used to calculate precision, accuracy/bias, completeness, comparability and sensitivity (if applicable) of the project data.

### Approach to managing unusable data

This section shall contain a description of what will happen if data are unusable, with particular emphasis on the impact of such unusability on data representativeness.