

OMB 0990-0115

**PART I - THE SCHEDULE**  
**SECTION A - SOLICITATION FORM**

Request for Proposal  
No. AHRQ-02-0015

Date Issued: July 5, 2002  
Date Due: August 9, 2002  
Time Due: 1:00 p.m. local time

Ladies and Gentlemen:

You are invited to submit a proposal to the Agency for Healthcare Research and Quality (AHRQ) for Request for Proposal (RFP) No. AHRQ-02-0015, entitled "Patient Safety Database." Proposals are being solicited on a **Total Small Business Set-Aside** basis under **North American Industry Classification System (NAICS) Code 541512 - \$18 million** for a two year contract for Phase I of the overall integration of Department of Health and Human Services (DHHS) event reporting and patient safety data systems.

Your proposal must be developed and submitted in accordance with the requirements and instructions of this RFP.

A Cost Reimbursement type contract is contemplated for a period of 2 years which would constitute Phase I of this effort. It is anticipated that a contract will be issued for Phases II and III upon completion of this contract.

Offerors shall submit the following:

- A. Technical Proposal (See Section L.9) - **Original and 10 copies**
- B. Past Performance Information (See Section L.10) - **Original and 4 copies**
- C. Business Proposal (See Section L.11) - **Original and 4 copies**

Your technical proposal must be concisely written and should be limited to **150 typewritten pages** (double-spaced), exclusive of personnel qualifications (i.e., resume, etc., see Section L.9 for additional details). This limitation is for administrative purposes only and exceeding the limitation shall not, of itself, be considered a basis for rejection of your proposal.

Your proposal must provide the full name of your company, the address, including county, Tax Identification Number (TIN), DUN and Bradstreet No., and if different, the address to which payment should be mailed.

**YOUR ATTENTION IS CALLED TO THE LATE PROPOSAL PROVISIONS PROVIDED IN SECTION L.3 OF THIS RFP. YOUR ATTENTION IS ALSO DIRECTED TO THE TECHNICAL PROPOSAL INSTRUCTIONS PROVIDED IN SECTION L.9 OF THE SOLICITATION.**

Questions regarding this solicitation shall be received in this office no later than **July 15, 2002** (See Section L.6). **Due to the time constraint of awarding this contract by the end of our fiscal year (September 30, 2002), no extensions will be issued on the due date of the proposal which is August 9, 2002.** Your questions should be submitted to the attention of Darryl Grant, Contracting Officer, Agency for Healthcare Research and Quality, Suite 502, 2101 E. Jefferson Street, Rockville, Maryland 20852 and the envelope should be marked "Proposal Questions RFP No. AHRQ-02-0015." **Discussions with any other individual outside the Division of Contracts Management, may result in rejection of the potential offeror's proposal.**

The proposal shall be signed by an authorized official to bind your organization and must be received in our Contracts Office no later than **1:00 p.m.**, local prevailing time, on **August 9, 2002**. Your proposal must be mailed to the following address:

Agency for Healthcare Research and Quality  
Division of Contracts Management  
2101 E. Jefferson Street, Suite 502  
Rockville, Maryland 20852

Hand carried proposals may be dropped off at the above location. The Division of Contracts Management offices are located in Suite 502 in the East Wing of the 5<sup>th</sup> Floor.

The RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

Requests for any information concerning this RFP should be referred to Mr. Darryl Grant, (301) 594-7189.

Sincerely,

Darryl Grant  
Contracting Officer, Division of Contracts  
Management  
Agency for Healthcare Research and Quality

## TABLE OF CONTENTS

<b><u>PART I</u></b>		<b><u>Pages</u></b>
Section A	Solicitation	1-2
	Table of Contents	3-4
Section B	Supplies or Services & Prices/Costs	5-6
Section C	Description/Specification/Work Statement	7-22
Section D	Packaging and Marking	23
Section E	Inspection and Acceptance	24
Section F	Deliveries or Performance	25-26
Section G	Contract Administration Data	27-29
Section H	Special Contract Requirements	30-36

### **PART II**

Section I	Contract Clauses	37-40
-----------	------------------	-------

### **PART III**

Section J	List of Attachments	41
-----------	---------------------	----

### **PART IV**

Section K	Representations and Instructions	42-60
Section L	Instructions, Conditions & Notices to Offerors	61-80
Section M	Evaluation Factors for Award	81-84

### **Attachments**

1. List of Reference Materials
2. List of Resources for Accessibility and Privacy Act Guidance
3. Implementation Planning Study for the Integration of Medical Event Reporting Input and Data Structure for Reporting to AHRQ, CDC, CMS, and FDA - Volume I - Technical Report
4. Implementation Planning Study for the Integration of Medical Event Reporting Input and Data Structure for Reporting to AHRQ, CDC, CMS, and FDA - Volume II - Appendixes
5. Barach P., Small SD Reporting and Preventing Medical Mishaps: Lessons from Non-medical Near Miss Reporting Systems. *BMJ* 2000; 320:759-763.
6. Battles JB, Kaplan HS, van der Schaaf TW, Shea CE. The attributes of medical event reporting systems. *Archives of Pathology Laboratory Medicine*; 1998; 122:3:132-138.

7. Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. *Acad Med* 2001;76:2:125-133.
8. Kaplan HS, Battles JB, van der Schaaf TW, Shea CE, Mercer SQ. Identification and classification of the causes of events in transfusion medicine. *Transfusion*. 1998 38: 1071-1081.
9. Past Performance Questionnaire and Contractor Performance Form
10. SF LLL-A, Disclosure of Lobbying Activities

**SECTION B-SUPPLIES OR SERVICES AND PRICES/COSTS**

**B.1 BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

“Patient Safety Database.” See Section C for a complete description.

**B.2 ESTIMATED COST AND FIXED FEE**

- a. The estimated cost (exclusive of fixed fee) of this two (2) year contract is \$\_\_\_\_\_.
- b. The fixed fee for this contract is \$\_\_\_\_\_. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the Clauses ALLOWABLE COST AND PAYMENT and FIXED FEE incorporated herein.
- c. The Government’s obligation, represented by the sum of the estimated cost plus fixed fee, is \$\_\_\_\_\_. The following is the total estimated cost plus fixed fee broken down by year:

	<u>Cost</u>	<u>Fixed Fee</u>	<u>Total</u>
Year 1	\$ _____	\$ _____	\$ _____
Year 2	\$ _____	\$ _____	\$ _____
Total	\$ _____	\$ _____	\$ _____

- d. Total funds currently available for payment and allotted to this contract are \$\_\_\_\_\_ of which \$\_\_\_\_\_ represents the estimated costs, and \$\_\_\_\_\_ represents the fixed fee.
- e. It is estimated that the amount currently allotted will cover performance of the contract through \_\_\_\_\_.
- f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor. For further provisions on funding, see the Limitation of Funds and the Allowable Cost and Payment (and Fixed Fee) clauses incorporated into the contract.

**B.3 PROVISIONS APPLICABLE TO DIRECT COSTS**

- a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated into this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

- (1) Acquisition, by purchase or lease, of any interest in real property;
  - (2) Rearrangement or alteration of facilities;
  - (3) Purchase or lease of any item of general purpose-office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
  - (4) Accountable Government property (defined as both real and personal property with an acquisition cost of \$1,000 or more, with a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property, 1990, regardless of acquisition value;
  - (5) Travel to attend general scientific meetings;
  - (6) Foreign Travel;
  - (7) Any costs incurred prior to the contract's effective date;
  - (8) Rental of meeting rooms not otherwise expressly paid for by the contract;
  - (9) Any formal subcontract arrangements not otherwise expressly provided for in the contract
  - (10) Consultant fees in excess of \$800/day; and
  - (11) ADP hardware or software.
- b. This contract is subject to the provisions of Public Law (P.L.) 99-234 which amends the Office of Federal Procurement Policy Act to provide that contractor costs for travel, including lodging, other subsistence, and incidental expenses, shall be allowable only to the extent that they do not exceed the amount allowed for Federal employees.

The Contractor, therefore, shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.205-46.

## **SECTION C**

## DESCRIPTION/SPECIFICATION/WORK STATEMENT

### **Patient Safety Database**

Independently and not as an agent of the Government, the Offeror shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work as described in the following sections.

#### **Background**

In November 1999, the Institute of Medicine (IOM) released a stunning report entitled, *To Err is Human* (1999), which estimated that between 44,000 and 98,000 people die each year in hospitals from medical errors. It called for a comprehensive and strong response to this most urgent issue facing the American people. The IOM called for leadership from DHHS in reducing medical errors and identified one of its operating divisions, the Agency for Healthcare Research and Quality (AHRQ), as the national focal point for patient safety research. As part of its reauthorization legislation, AHRQ is required to direct efforts at reducing errors in medicine. Specifically, the Director shall conduct and support research and build private-public partnerships to (1) identify the causes of preventable health care errors and patient injury in health care delivery; (2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and (3) disseminate such effective strategies throughout the health care industry. In carrying out these responsibilities, the Agency has developed a coordinated plan for achieving these three goals that includes projects funded through grants, cooperative agreements and contract mechanisms.

A major focus of the patient safety agenda has centered around issues of identification of errors and risks to patient safety through event reporting. Barach and Small (2000) (attached as a PDF file, **Attachment 5**) reviewed the literature on non-medical event reporting systems such as those in aviation, nuclear power and the petrochemical industries for clues to their success which could potentially be applied to risk identification in healthcare. They found that the quality and success of incident reporting systems for both actual accident and close call events depends upon immunity (as far as practical), confidentiality or data de-identification (making data untraceable to care givers, patients, institutions, and time), independent outsourcing of report collection and analysis by peer experts, rapid meaningful feedback to reporters and all interested parties, ease of reporting, and sustained leadership support. Battles et. al.(1998) (attached as a PDF file, **Attachment 6**) identified the ideal attributes of medical event reporting systems. These attributes included: 1) integration of the reporting system with institutional Quality Assurance (QA) and patient safety activities so that the system could be used as a local patient management tool; 2) capability to deal with a high volume of reports; 3) inclusion of selection or screening process to sort reports as routine events or new or unique incidents, and 4) the ability to provide a consistent method of classification as to the type of event, where in the process of care it occurred and the root cause that could be used by existing quality assurance/risk management personnel without extensive training. Kaplan et. al. (1998) (attached as a PDF file, **Attachment 7**) described a methodology to determine underlying causes of error or events that can be used with medical event reporting systems.

One component of the federal strategy to identifying risks to patient safety and solutions to mitigate those risks is promoting the use of data currently collected by federal agencies. This effort is complicated by the fact that there is no national reporting system, and systems mandated by State legislatures only collect rates of catastrophic events, such as deaths and life-threatening events from medical mismanagement. There are, however, a number of extant Federal systems of records on adverse medical events exist. Within the Department of Health and Human Services, the Food and Drug Administration (FDA) collects information on adverse events related to medical products, the Centers for Disease Control and Prevention (CDC) conducts surveillance on adverse events related to public health concerns – nosocomial infections, vaccines, and dialysis, the Centers for Medicare and Medicaid (CMS) monitors the quality and safety of care provided to beneficiaries, and AHRQ is responsible for assessing the quality and safety of health care nationwide. Other Departments in the federal government also have active programs related to patient safety reporting. For example, the Department of Veterans Affairs (VA) has a progressive program to reduce medical errors in the Veterans health care system. The Department of Defense and the Indian Health Service also are focusing on the quality and safety of their health care systems.

There are also a number of recent and emerging reporting systems in the private health care sector. These private reporting systems usually assemble error data only after it has been stripped of its patient, provider, and institutional identifiers. Many of these systems are now using the Internet as a medium for medical error reporting. Because some error reporting (if only internal to the facility) is required for accreditation it is expected that the number of systems in the private sector will increase rapidly over the coming 3 years.

For many reasons, the integration and streamlining of reporting systems should improve information and benefit health care. One concern of health care providers and purchasers is that proliferating reporting systems, especially mandated ones, are confusing and burdening health care providers. Another concern of policy makers is that reporting is uneven, uninformative, and plagued with problems. In addition, medical errors are acknowledged to be grossly under-reported. Additional reporting systems are unlikely to solve that problem. Fewer, simpler, coordinated and fully protected reporting systems have a better chance. The Secretary of the U.S. Department of Health and Human Services (DHHS) has established a *Patient Safety Task Force (PSTF)* with the mission to integrate existing data collection on medical errors and adverse events, to coordinate research and analysis efforts, and to collaborate on reducing the occurrence of injuries that result from medical error. The PSTF brings together AHRQ, CDC, CMS and FDA to integrate and coordinate their activities related to patient safety and the reduction of medical errors. To initiate this effort, the PSTF contracted with MEDSTAT Group, Inc. for an implementation planning study which recommended a phased integration process with three distinct phases.

#### Phase I

This phase begins by developing a common user interface for those systems that collect adverse event information from facilities. Specifically, this approach calls for development of a common user interface for three FDA systems:



- Adverse Events Reporting System (AERS),
- Biological Product Deviation (BPD),
- Manufacturer and User Device Experience (MAUDE), and
- CDC system: National Healthcare Safety Network (NHSN).

Integrating the data collection component of these systems would provide facilities with a web-accessible common user interface that allows for standardization of data elements common to each system. As part of Phase I, a front end would be developed that collects information using a consistent look and feel, and routes information to existing data stores at the respective Agencies. The contractor shall develop a new web site which would serve as the single point of contact for all hospital-based event reports to the CDC and the FDA. This point of contact will consist of a web site on the public Internet accessed by pointing a browser to a single distinct URL, although in fact the site may consist of one or more new and/or existing web server computers or processors. The new web site will prompt for and receive all of the variations of event reports that are currently being collected as part of the four systems and be designed to limit reporter burden.

## Phase II

Phase II is intended to tackle breadth of scope first, integrating all four systems across two agencies - but to attempt only the visible front-end integration at first, and to extend the scope of development to the data store and analytic reporting functions later. The metaphor is horizontal integration first, vertical integration in subsequent phases. Phase II is devoted to developing a common data model and migrating data from the four systems into this new model. Additionally, this phase will include other data sources, derived from administrative data systems, that will assist in providing benchmarks and appropriate denominators to augment the reporting functions already in place.

## Phase III

Phase III is a continued expansion of the system horizontally, adding additional non-DHHS systems. These systems include event reporting systems operated by individual States, the VA, the DoD, the NRC, JCAHO, and other national systems, specifically that of the United Kingdom. The MEDSTAT contract final report entitled *Implementation Planning Study for the Integration of Medical Event Reporting Input and Data Structure for Reporting to AHRQ, CDC, CMS, and FDA* is included as an attachment to this solicitation (**Attachments 3 and 4**). It is suggested that the MEDSTAT report serve as a guide for the development of a response to this solicitation. The PSTF through AHRQ is soliciting proposals for a contract for Phase I of the overall integration of DHHS event reporting and patient safety data systems. The three phases will be separate contract activities with Phases II and III to be contracted for upon completion of this contract for Phase I.

## Objectives

The overall purpose of the three distinct phases is to translate the recommendations of the implementation planning report and to develop an operational patient safety network.

Under this initial contract for Phase I, the contractor shall provide support in: (1) the development of a web based reporting interface for hospital and institutional-based reporting of events to the CDC and FDA which includes the FDA's Adverse Events Reporting System (AERS), Biological Product Deviation (BPD), Manufacturer and User Device Experience (MAUDE/MedSun), Vaccine Adverse Event Reporting System (VAERS) and the CDC's National Healthcare Safety Network; (2) the development of a coding structure for reporting; (3) the development prototype data warehouse and query system of event reports; (4) the development of training materials and user-based software for local institutional use; (5) prototype testing of the reporting system; and (6) the development of an integration plan for Phases II and III. Development and implementation of Phase II and Phase III are to be separate contractual activities and not included as part of the scope of work for this initial Phase I development contact.

### 1. Specific Requirements

*Specifically, the contractor shall:*

Design and carry out the phased implementation of an integrated patient safety event reporting and data collection system for the four participating DHHS partners (AHRQ, CDC, CMS, and FDA) and provide linkages to other non-DHHS organizations such as other federal reporting system of the DoD, NRC, and VA, state departments of health, and other countries. Under Phase I, the contractor shall develop and implement a common web-based user interface to integrate the reporting of five current reporting systems: CDC's National Healthcare Safety Network (NHSN), FDA's Adverse Events Reporting System (AERS), Biological Product Deviation (BPD), Vaccine Adverse Event Reporting System (VAERS), and Manufacturer and User Device Experience (MAUDE)). The Medical Product Surveillance Network (MedSun) is being developed as an adjunct and eventual replacement for MAUDE. Therefore, in the development of Phase I, it is important to work with both MAUDE and MedSun.

#### 1.1 Plan for Phase I

In Phase I, the common agency web server will serve only as a mechanism for eliciting event reports from users and forwarding the information to the appropriate agency systems. The permanent persistent storage of reports and the subsequent analysis and reporting shall continue to take place at the systems maintained by the agencies for this purpose.

Planning consideration shall be given to the potential number of users and the potential size of the data generated by the system. Currently, there are over 7,000 hospitals in the United States, excluding those of the VA and DoD. Within those hospitals, there are 823,565 operational beds. If one uses a planning figure of an institution reporting an average of one event (including no

harm and near misses) per bed per month, then the total number of event reports would be in excess of 9,882,780 reports per year nationwide. Thus, planning for significant volume of potential reports is essential.

The main functions of the common agency web server shall be to:

- Authenticate users, when appropriate and necessary
- Determine the information to collect from users, present forms for this purpose and validate information in the event reports to the greatest extent possible
- Acknowledge receipt of information from users with a unique confirmation number that identifies the interaction that occurred
- Allow users to amend, retract or otherwise update reports after establishing their right to do so
- Reliably transfer the event reports and the updates to the appropriate system(s) at the FDA and CDC sites.

In development of the web-based front end, the contractor shall meet all Federal government requirements for web pages including DHHS guidelines for web pages. (see **Attachment 2**)

Within 8 weeks of the effective date of contract, the contractor shall deliver the plan for Phase I to be reviewed by the contractor's External Advisory Panel and the PSTF for approval.

## 1.2 External Advisory Panel

The contractor shall create an External Advisory Panel (EAP) composed of representatives from health organizations who would have a stake in integrated medical event reporting (i.e., health care professionals who would be reporting to or using an integrated medical event reporting/data system for medical event tracking and research)). Specifically, EAP members shall be selected from the following groups:

- providers of health care services,
- producers of health care products,
- policymakers in the patient safety arena,
- researchers in patient safety and related fields, and
- representatives of patient and or consumer groups

These representatives shall help guide the work of the contract so that it meets the needs of relevant constituencies. In addition, organizations with a mission focused on patient safety or healthcare quality shall be included to influence activities that would result in support of a national reporting and data system. For planning purposes, that panel should be made up of between 12 and 15 individuals including one representative from the United Kingdom's National Patient Safety Agency (NPSA) of the National Health Service (NHS). The contractor shall be responsible for arranging meetings, including costs of honoraria and travel by the EAP. Nominations for members of the panel will be furnished by members of the PSTF. The panel should meet twice a year to review the progress on the development of the system and to provide

advice to the contractor on the project.

### 1.3 Coding and classification

There is considerable debate in some circles about whether there should be coding and classification of event reports. While total reliance on narrative has been the norm for most small scale reporting systems, analysis and consistency of data has been a considerable problem that has limited the utility of many event databases. In fact, reliance on narrative formats has often precluded the creation of electronic databases. Thus, many event reports end up in a paper graveyard. If one begins to assemble large databases of events in the hundreds of thousands, then coding is required. A combination of structured narrative and coding has the greatest promise for utility both in reporting and in analysis. Thus coding and classification are needed for the various components of an event described above. The contractor shall include a coding scheme that should be universal and not limited to any medical domain or problem area. It shall be compatible with existing coding methods currently used in healthcare such as the International Code of Diseases (ICD 9/10) and be compatible with the unique coding requirements and systems used by FDA, CDC, CMS, and AHRQ. The contractor shall evaluate all of the existing coding schemes of the existing systems with the FDA and CDC, specify their pros and cons, and make specific recommendations to the PSTF for final approval prior to implementation.

1.3.1 *What* happened is the description actual or potential harm or injury to a patient - iatrogenic injury.

The what shall be in context of the iatrogenic injury. The E codes of the ICD contain injury classifications but at present are inadequate for iatrogenic injury. A specific set of E codes shall be developed within the framework of ICD. The advantage of creating iatrogenic injury E codes is that ICD codes are worldwide and accepted in health care delivery and record keeping. In order for ICD-10-CM to be suitable for error reporting, considerable attention must be paid to its modification in this regard. The ICD-10-CM workgroup and experts in patient safety shall collaborate on concepts, terms, and classifications. This will require the ICD-10-CM workgroup to do a thorough analysis of the improvements of ICD-9-CM and ICD-10-CM with respect to misadventures and medical errors. This also requires the patient safety research and quality improvement communities to become involved in improving the classifications of the ICD in order to make it relevant to safety concerns.

The contractor shall form a workgroup to develop a set of iatrogenic E codes that shall serve as a special set of the ICD codes. This workgroup shall be made up of patient safety ICD coding experts. The contractor shall use a consensus development process to formulate the recommended codes. The contractor shall also use the Patient Safety Indicators developed under contract to AHRQ as well as from triggers and medical record indicators being used by CMS for the Medicare Patient Safety Monitoring System (MPSMS). These materials shall be furnished to the contractor upon award of the contract. The contractor shall work with the NCVHS activity to ensure that the coding structure meets all the requirements of the ICD coding framework and is submitted to the WHO for inclusion for the annual modification of the ICD codes. Actual approval of the recommended codes is beyond the scope of this contract and is a function of the

NCVHS itself. It is essential that the coding structure also be linked with the FDA MedDRA coding structure and not replace it but rather enhance the linkage with other administrative data systems such as those currently used by AHRQ, CMS, and CDC.

AHRQ has contracted with the IOM to develop guidance on the nature and structure of patient safety data. This contract, Patient Safety Data Guidance, is currently developing the needed guidelines for event reporting systems and other patient safety data. The contractor shall be responsible for using these guidelines and guidance when published by the IOM. The results of this contract will be published by the IOM in October 2003. The details of this existing contract can be found on the IOM web site at [www.IOM.edu/psdg](http://www.IOM.edu/psdg). The contractor will work closely with the IOM project staff to coordinate the activities of this project and the data guidance activities of the IOM.

1.3.2 Where in the process of care currently lacks a standard for coding.

It is critical to be able to describe where in the process an event and its antecedents were discovered. In many instances, an adverse event may have been initiated in one stage of the care process but not discovered until the patient is in another stage of care. The contractor shall develop a system of classifying where in the system an event occurred.

1.3.3 When is merely a date and time and needs no special coding.

1.3.4 Who was involved

Who is a listing of those healthcare providers, without specific identification, that were involved and is easily coded by existing methods. This aspect of who shall be limited to the generic classification of the type of practitioner rather than any individual identification that would violate privacy and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements.

1.3.5 Why coding must come from the results of a root cause analysis.

There are a number of existing causal classification systems currently being used including systems developed by the VA and other organizations. The Eindhoven Classification Model (ECM) (medical version) is another system that has been successfully tested in a number of different medical domains and found to be valid and reliable. As a result, it should be considered as a candidate system along with other extant classification schemes. The candidate root cause classification system should be based on the theoretical structure of human error behavior of Rasmussen (1984, 1987) and the concept of latent conditions as expressed by Reason (1990, 1997). It should also be domain independent so that it would be possible to examine the root causes of events from multiple industries such as petrochemicals, steel, and telecommunications with those within medicine.

### 1.3.6 Patient information

This information already exists within the structure of the ICD coding. The patient information must not contain personal identification and be in compliance with HIPAA and other prevailing privacy requirements.

### 1.3.7 Product information

MedDRA and other classifications have been developed by the FDA for biologics, drugs, and devices. There is a need for some integration of existing classification modalities, however a frame does exist as a starting point. Again it is essential that the coding structure be compatible with the needs of the various FDA components (with CBER, CDER, and CDRH) as well as the needs of the CDC, CMS, and AHRQ.

### 1.3.8 Risk Assessment Index

Risk assessment indexing is an essential component of the system that is necessary for determination of the overall event severity level or ESL. Thus, each event shall be classified using risks assessment indexing or severity assessment coding. Two candidate risk assessment indexing approaches already exist, one developed by the VA ([www.patientsafety.gov](http://www.patientsafety.gov)) and one developed by the MERS-TM system([www.mers-tm.net](http://www.mers-tm.net)). Both systems are simple and can easily be incorporated into the reporting format. The risk indexing process shall include the recording of both the actual and potential severity and probability of recurrence separately, then automatically calculate a single risk index. Both the severity and probability figures are to remain in the record of the event along with the resulting risk index. Again, the risk assessment indexing system must also be compatible with assessment of product risks for drugs, vaccines, infections, and devices.

### 1.3.9 Structured narrative

Structured narrative shall be used to amplify the coded information in text fields to provide detailed information about the event reported. The use of a causal tree format shall be used to capture the narrative amplification.. Battles (2001) (attached as a PDF file, **Attachment 8**) provides examples of the structured narrative of event reports. These causal tree formats shall be coded in the database in such a way that the causal tree can be recreated in graphical form when the event data is retrieved.

## 1.4 Authenticating Users

The existing FDA systems and the NHSN currently collect event reports under a variety of user authentication and identification scenarios. Some event reports to the FDA systems can be made anonymously whereas others are made by identified reporters. Event reports submitted to the NHSN system will be by identified, registered reporters only, and with a computer certificate-based system used to positively establish the reporter's identity and authenticity. The common agency web server shall accommodate each of these types of event reporting.

## 1.5 Soliciting Information

The primary purpose of the common web server shall be to elicit data on adverse events reported by facilities that are currently collected by the CDC and the FDA in a manner which lowers the current reporter burden.. The common web server shall maintain a “Forms Library” attached to the web server. This library shall contain all of the *static* HTML forms needed to collect information now collected as part of NHSN, BPD, MAUDE/MedSun, VAERS, and the AERS. The qualifier “static” in the previous sentence acknowledges that some of the information collected (via NHSN) shall be determined by database entries that effectively customize a facility’s set of forms..

## 1.6 User Interface Characteristics

It is a crucial, defining principle of the system that the set of information gathering forms be as simple, efficient and easy to use as possible from the point of view of the end user. To this end, the design effort shall look at the total collection of forms used by the four agencies and strive to remove redundancy from reporting, streamline the process used to enter information, and introduce as much consistency as possible. Font styles, sizes and colors can be chosen to provide consistent information to users across all the systems. All requirements of accommodation to the handicapped under Public Law 508 must be met.

The interface must comply with appropriate web development regulations, and be aimed at minimizing the burden of reporting that the user must tolerate. This can be achieved by minimizing the number of keystrokes and mouse clicks a user must make, and by minimizing the shuffling and reorganizing of information, both cognitive and physical, that the user must perform to accomplish the reporting task.

## 1.7 Confirming Report Receipt

Once the report has been received, its receipt will be confirmed by the system. This will be done by generating a unique confirmation number and reporting it back to the user. The contractor must develop a confirmation system that will accommodate the needs of all the participating agencies and yet accomplish a systematic receipt process.

## 1.8 Creation of the Forms Library

The contractor shall seek to develop a common front-end, with a consistent look and feel, to the data gathering elements of what are now five disparate systems. To this end, the contractor must create an environment that can be used to meld visible elements of the five sites into a single coherent site.

## 1.9 Common Templates

To promote a common look and feel, the forms library shall begin with a collection of common HTML templates. These templates shall contain elements such as:

- The headings, hyperlinks and logos used on every page,
- The common high-level navigation bar that runs down the side or across the top,
- A common footer that includes things such as links to help, frequently asked questions, and a way to contact site personnel,
- HTML table definitions used to divide web pages horizontally and/or vertically and to control how elements wrap or truncate as the page is expanded or narrowed in the user's browser,
- Frames and borders, and their respective colors and widths
- Other common elements

Other templates might contain one or more common, pre-populated controls, such as:

- Drop-downs for identifying physical locations, such as States,
- Drop-downs, list boxes or JavaScript-based hierarchical indexes for displaying common taxonomies,
- Text boxes with scroll bars for free-text data entry,
- Collections of patient-description information, such as ID, age, DOB, sex, weight, etc., formatted together in a standard way,
- Combinations of descriptive text and labeled check boxes laid out in a standard fashion
- Mouse-over effects such as highlighting, descriptions, help text and tips
- Date capture boxes that qualify dates and optionally display calendar controls

#### 1.10 Graphical elements

Whereas as a common template library provides a repository of HTML that can be shared and reused across the five sites, a graphics library can serve the same purpose for graphical elements used in the site, helping to provide a common coherent look and feel to the entire site. Graphical elements might include things such as:

- DHHS logo,
- FDA and CDC agency logos,
- Program logos such as "MedWatch",
- Backgrounds,
- Pictures,
- Maps,
- Gradients,
- Curved or shaped boundaries and filled areas
- Distinctive buttons,
- Text formatted as graphics to preserve a particular font and/or layout

#### 1.11 Routing Information

Based upon the type of information the user is reporting, the common front-end shall route the adverse event description information to the appropriate back-end web site(s). In the situation where the information might be appropriately reported to more than one site, the system shall



automatically route the information to multiple sites, or give the user the option to forward the information to multiple sites. Depending on the complexity of the interaction, however, additional types of information might need to be routed between the agency sites and the common front-end.

### 1.12 Data Warehousing Prototype

Although the initial thrust of Phase I is the development of a common front-end web site for four FDA and CDC systems, the ultimate goal of all three Phases is true end-to-end integration of these and other systems. Ultimately, the disparate data models these systems utilize will need to be reconciled into a single homogenous model that will support integrated reporting. Rather than wait until the common front-end has been built and is operational, it is highly desirable that the issues involved with data integration be confronted as quickly as possible, so that any changes in data collection required to support integrated reporting can be discovered as early as possible and incorporated into the developing system. This can best and most quickly be accomplished by going through the process of building a prototype data warehouse from the existing databases behind NHSN, AERS, MAUDE/MedSun, VAERS, and the BPD.

The purpose of this prototype, unlike a classic data warehouse, will not be to maintain a current, up-to-date, real-time data query facility, but rather to investigate issues of data quality, data completeness, data linkage capabilities, homogeneity and conceptual compatibility. As such, the prototype will not have to deal with the standard data warehouse issues of timing and periodic updating. It is envisioned that a process whereby a static “snapshot” of each database is taken encompassing approximately one year of the most recently collected data will be used to create this prototype.

The five snapshots should be moved onto a single analytic platform, combined and analyzed. Based upon current estimates of data volume for the five systems involved, this platform need not be more elaborate than a workgroup or department server with 100 to 200 GB of disk storage. There are a number of commercially available software tools that could be used to facilitate the process, including ETL (“Extract, Transform and Load”) packages and statistical packages that incorporate data manipulation tools.

A user driven search mechanism shall be built into the data warehouse and front-end interface which shall allow authorized hospital or institutional users to generate queries of the data warehouse. The query mechanism shall use a form of case-based reasoning or fuzzy matching to allow end-users to take an existing event and query their local database and the data warehouse to determine if there are any matching events and if so how many have occurred. A description of such an operating query mechanism can be found at [www.MERS-TM.net](http://www.MERS-TM.net).

### 1.13 User-based software

As part of the development of the system, the contractor shall develop a user version of the front end entry system and the prototype data warehouse that can serve as an local institution's own event reporting system and database. The institution user-based version of the software should

allow participating institutions the ability to maintain their own local system using the design parameters of the national system.

#### 1.14 Develop user training materials

The contractor shall develop user training materials that will enable hospitals and other users of the system to be able to develop the skills necessary to use the event reporting system to its maximum. These materials shall be in the form of a flexible training kit or FLEXTRAKIT (Battles 1989) which will contain operating instructions and practice opportunities to gain proficiency with the new reporting systems. The contractor shall provide a minimum of four training workshops for potential users which will demonstrate the training kit. The sites for the training shall be determined by the location of participants in the prototype testing. These workshops shall be in the form of train the trainer activities. The training materials shall be web accessible, and downloadable, and in the public domain so that local health care institutions can obtain their own copies of the training kit for local use.

#### 1.15 Conduct prototype testing Phase I

The contractor shall conduct prototype testing of Phase I integration and the prototype data warehouse with a representative sample of institutional users of the system before complete roll out of the Phase I product. The contractor shall, with the assistance of the PSTF, recruit approximately 50 hospitals nationwide that shall test the prototype system. The prototype testing shall be conducted over a six month period. The contractor shall test the training materials as part of the prototype testing process.

#### 1.16 Revise the system based on testing

The contractor shall make whatever changes are necessary to the system design and operating characteristics based on the results of the prototype testing.

#### 1.17 Phased roll over to new front-end

Nation-wide roll-out of the new reporting system front end will be accomplished once all testing has been completed. Training materials shall be distributed prior to roll out to allow all institutions to become familiar with the new system prior to full operation.

#### 1.18 Hardware Requirements

At this time, it is anticipated that the production hardware will be maintained and operated at AHRQ. The contractor shall be responsible for furnishing the necessary development system(s) at their own site and expense.

## 1.19 Plan for Phases II and III

The contractor shall develop a detailed plan for the development of Phase II and Phase III. Phase II shall be the development and implementation of the integration of the data storage and analysis for the four systems and other DHHS patient safety systems. Prior to the completion of Phase I, the contractor shall prepare a detailed plan for the integration of the existing data bases of the systems of the FDA and CDC. This integration will involve the planning and design of a patient safety data warehouse based on the prototype developed in Phase I. In addition to the existing databases, the plan will include the integration of administrative data systems from AHRQ and CMS as well as other candidate systems nominated by the PSTF. This plan shall include an update and modification of the original plans contained in the contractors initial proposal.

### 1.19.1 Integrating the Data Store

A multi-tiered architecture is required, with separate, independent “layers” that handle, in order:

- The visible user interface
- The logic required to present and accept data from the user interface
- Message queuing, if it is incorporated
- Business logic, computed values and enterprise “rules” that must be enforced
- Stored procedures that extract and insert data from the relational database, and implicit procedures such as database triggers and referential integrity rules
- The logical and physical structure of the underlying relational database(s)

There are a number of outstanding third party tools that do an excellent job of abstracting physical structure from one database platform (such as DB2 or SQL Server) and importing it to another (such as Oracle). Once the physical structure has been recreated on the new platform, the data can be migrated table by table. Once the standard platform is chosen, all physical structure, stored procedures and business logic can be migrated onto this platform.

### 1.19.2 Analysis and Reports

Concurrent with planning to transition to the common data store, decisions are needed as to the physical location and machine resources necessary to perform analysis and reporting. Recall that in Phase I, the data store and the analysis/reporting for each of the four systems will continue to be at the original agency sites. Once the data store is moved to a common location, the decision will need to be made as to where analyses will occur. Consideration shall be given to determine the computing and storage resources necessary to subsume the reporting requirements of the previously separate systems into one common system. This plan must also take into account all relevant data security and confidentiality regulations.

### 1.19.3 Adding Administrative Data

As part of Phase II, moving some form of administrative data derived from CMS Medicare and Medicaid research databases and AHRQ's HCUP-derived hospital patient data is essential.

### 1.19.4 Non - DHHS Integration

The contractor shall plan implementation for Phase III, the integration of non-DHHS reporting systems. System to be included in the integration are other federal reporting systems including the VA, DoD, and the NRC. The growing number of state reporting systems will be included in the integration process as well. The contractor, with the assistance of both the External Advisory Panel and the PSTF, shall identify likely state candidates to be included. Major systems, such as JCAHO, are to be invited for inclusion included in Phase III as well as systems operated by other nations including the UK, Japan, Australia, Denmark.

### 1.20 Evaluation

The contractor shall work closely with AHRQ Patient Safety Program Evaluation Center in the development of an external evaluation that documents the impact and adoption of the integrated federal reporting system. The overall responsibility for program evaluation will rest with that of the AHRQ's Evaluation Center. The contractor shall be responsible for maintaining adequate documentation of the development process and actions taken during the process of the development of the reporting system so, that the Evaluation Center can complete its assessment and evaluation. The contractor shall be responsible for the formative evaluation that is associated with prototype testing and usability analysis of the system during development. The records and data associated with such formative evaluation shall be made available to the contractor serving as AHRQ's Patient Safety Program Evaluation Center.

## **2. Project Management**

Because this project is a cooperative activity of four agencies within DHHS, there will be a cooperative management structure used for the contract management. While the contract itself is with AHRQ and the official Contract Officer and Project Officer will be from AHRQ, there will be additional agency coordinators, one from each of the other agencies: PSTF, CDC, CMS, and FDA.

- 2.1 Within one week of the effective date of the contract, the contractor shall meet with the AHRQ Project Officer, the agency coordinators from CDC, CMS, and FDA, as well as other essential patient safety team members at AHRQ and other participating agencies specified by the Project Officer. The meeting shall be used to review and clarify the scope of work and delivery schedule for this task, to delineate roles and responsibilities, and to establish communication protocols.
- 2.2 Based on discussions with the Project Officer and others specified by the Project Officer, develop a draft Phase I plan for Project Officer approval.

- 2.3 Revise the plan based on results of the review by the Project Officer and agency coordinators and submit the final work plan to AHRQ Project Officer.
- 2.4 The contractor shall prepare 5 copies of a monthly progress report in electronic and paper format and deliver to the Project Officer (10) days after the month being reported. The report shall state in concise form:
- A short description of the project objectives
  - A brief narrative on what was actually accomplished completing each assigned task during the reporting period, and a summation of the cost and level of effort expended for each Task
  - Preliminary or interim results, conclusions, trends, or problems that the contractor feels should be of concern to the Government
  - Problems or delays that the Contractor has experienced in the conduct of performance requirements including what specific action is proposed to alleviate the problem(s)
  - What is planned for accomplishment during the next reporting period including anticipated staffing requirements in cost and level of effort?
- 2.5 Design develop, validate, and implement the coding and classification scheme for the user front end. Formulate a workgroup to develop iatrogenic injury E Codes for the ICD 10 and prepare a report for the NCVHS for submission for inclusion in annual ICD modifications and change process. Prepare necessary OMB clearances packages for AHRQ's submission to DHHS for OMB approval.
- 2.6 Submit a draft of training materials and user-based software for Project and agency coordinator's review and approval. Based upon the review, revise the training materials and user-based software as needed and/or required.
- 2.7 Demonstrate the prototype event reporting system including the training materials, user- based software, web based data entry system, the prototype data warehouse, and user driven query and feedback system and to the External Advisory Panel and the PSTF.
- 2.8 The contractor shall submit 5 copies of a plan for Prototype Testing including a list of participating hospitals and other health care institutions approved by the Project Officer and agency coordinators. Upon approval of the Project Officer, the contractor shall implement the plan and conduct the prototype test with a minimum of 50 hospitals and healthcare institutions.
- 2.9 The Contractor shall prepare and submit 5 copies of a report on the results of prototype testing.
- 2.10 The Contractor shall submit a revised plan, based on the results of the prototype testing for the nationwide Phase I implementation of the event reporting system.

- 2.11 The contractor shall submit 5 copies of a detailed implementation plan for Phase II, data integration and design of the data warehouse. A and Phase III implementation plan for the potential inclusion of other reporting systems outside DHHS, including but not limited to VA, DoD, NRC, JCAHO, and State systems, must also be. to be submitted to the Project Officer and Co-Project Officers for approval.
- 2.12 Submit draft and final reports including a separate executive summary. The content and format of these reports shall be determined in consultation with the Project Officer and Co-Project Officers.
- 2.13 Make a formal presentation to AHRQ and the PSTF of the final results of the project. The content and format of the presentation shall be determined in consultation with the Project Officer and Co-Project Officers.
- 2.14 The contractor shall submit all masters for training materials and user software including codes and assure copyright clearance of all material contained within the deliverable so that there are no impediments to in releasing products from this contract materials as public domain resources.

## **SECTION D - PACKAGING AND MARKING**

The Contractor shall mark each delivery with the organizations name, contract number, item number, and quantity (indicating partial, full or final shipment. As appropriate, note on the face page of the report and when feasible on the binding (1) "one volume only" or (2) "volume 1 of 2, volume 2 of 2" etc.

## SECTION E - INSPECTION AND ACCEPTANCE

### E.1 INSPECTION AND ACCEPTANCE

- a. The contracting officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION the Government Project Officer is the authorized technical representative of the contracting officer.
- c. Inspection and acceptance will be performed at:

Agency for Healthcare Research and Quality  
Executive Office Center  
2101 East Jefferson Street  
Rockville, Maryland 20852

### E.2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

**FAR Clause No.**

**Title and Date**

52.246-5

Inspection of Services-Cost Reimbursement  
(April 1984)



**SECTION F - PERIOD OF PERFORMANCE AND DELIVERY SCHEDULE**

**F.1 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)**

This contract incorporates the following clause by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

**FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES**

<b>FAR Clause No.</b>	<b>Title and Date</b>
52.242-15	Stop Work Order (AUG 1989) Alternate I (APRIL 1984)

**F.2 PERIOD OF PERFORMANCE**

The period of performance for shall be as follows, unless extended by modification to this contract:

Year 1	October 1, 2002 through September 30, 2003
Year 2	October 1, 2003 through September 30, 2004

**F.3 DELIVERY SCHEDULE**

The items specified for delivery below are subject to the review and approval of the Project Officer before final acceptance. The Contractor shall be required to make revisions deemed necessary by the Project Officer.

The Contractor shall produce the following scheduled reports/deliverables in the amount, and within the time frame indicated. Deliverables shall be submitted to the Project Officer, Agency for Healthcare Research and Quality (**Address To Be Completed at Time of Contract Award**). Draft deliverables are those submitted to the Project Officer for review. Final deliverables are those incorporating changes requested by the Project Officer.

The Contractor shall submit the following items in accordance with the stated delivery schedule:

<b>Item</b>	<b>Task</b>	<b>Description</b>	<b>Quantity</b>	<b>Delivery</b>
1	2.1	Meet with Project Officer, Co-Project Officers and the PSTF	--	1 week from EDOC
2	1.1, 2.2	Submit draft Phase I plan	5 (4 hardcopy & 1 electronic)	8 weeks from EDOC
3	2.3	Finalize Phase I Plan	5 (4 hardcopy & 1 electronic)	12 weeks from EDOC

4	2.4	Submit Progress Report	5 (4 hardcopy & 1 electronic)	Monthly
5	2.5	Submit Report on Classification Approval	5 (4 hardcopy & 1 electronic)	6 months from EDOC
6	2.6	Submit draft of training material kit and user based software	5 (4 hardcopy & 1 electronic)	12 Months from EDOC
7	2.7	Demonstrate prototype system to External Advisory panel and PSTF	--	15 months from EDOC
8	2.8	Submit plan for phased roll out and prototype testing of Phase I	5 (4 hardcopy & 1 electronic)	15 months from EDOC
9	2.9	Submit report on results of prototype testing	5 (4 hardcopy & 1 electronic)	22 months from EDOC
10	2.1	Submit implementation plan for Phase II	5 (4 hardcopy & 1 electronic)	20 months from EDOC
11	2.11	Demonstrate Prototype Data Warehouse and reporting and analysis to External Advisory Panel and PSTF	--	18 months form EDOC
12	2.12	Submit draft of final project report	5 (4 hardcopy & 1 electronic)	22 months form EDOC
13	2.13	Make formal presentation to PSTF	5 (4 hardcopy & 1 electronic)	23 months from EDOC
14	2.14	Submit final master of all training materials and user software including codes and copyright clearances	5 (4 hardcopy & 1 electronic)	24 months from EDOC

**EDOC - Effective Date of Contract**

The above items shall be addressed and submitted to the Government Project Officer. In addition, one copy of the monthly and final report shall be submitted to the Contracting Officer at the following address:

Agency for Healthcare Research and Quality  
ATTN: Contracting Officer  
Division of Contracts Management  
2101 East Jefferson Street, Suite 502  
Rockville, Maryland 20852

## SECTION G - CONTRACT ADMINISTRATION DATA

### G.1 KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I.5 of this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME

TITLE

**(TO BE COMPLETED AT TIME OF CONTRACT AWARD)**

The clause cited above contains a requirement for review and approval by the Contracting Officer of written requests for a change of Key Personnel reasonably in advance of diverting any of these individuals from this contract. Receipt of written requests at least 30 days prior to a proposed change is considered reasonable.

### G.2 PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

**(TO BE COMPLETED AT TIME OF CONTRACT AWARD)**

The project officer is/are responsible for: (1) monitoring the contractor's technical progress, including the surveillance and assessment of performance and recommending to the contracting officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The contracting officer is the only person with authority to act as an agent of the Government under this contract. Only the contracting officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the contractor of any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

### G.3 INVOICE SUBMISSION

#### a. INVOICE SUBMISSION

Billing Instructions are attached and made part of this contract. Instructions and the following directions for the submission of invoices must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9, and must be in accordance with the General Provisions clause 52.232-25 Prompt Payment (FEB 2002).

Invoices/financing requests shall be submitted in an original and five copies to:

Contracting Officer  
Agency for Healthcare Research and Quality  
Division of Contracts Management  
Executive Office Center  
2101 East Jefferson Street, Suite 502  
Rockville, Maryland 20852

#### **G.4 INFORMATION ON VOUCHERS**

- (1) The Contractor agrees to include the following minimum information on vouchers:
  - (a) Contractor's name and invoice date;
  - (b) Contract Number;
  - (c) Description and price of services actually rendered;
  - (d) Other substantiating documentation or information as required by the contract;
  - (e) Name (where practicable), title, phone number, and complete mailing address or responsible official to whom payment is to be sent; and
  - (f) The Internal Revenue Service Taxpayer Identification Number.
- (2) The Contractor shall furnish the following minimum information in support of costs submitted:
  - (a) Direct Labor - include all persons, listing the person's name, title, number of hours or days worked, the total cost per person and a total amount of this category;
  - (b) Fringe Costs - show rate, base and total amount as well as verification/allowability or rate changes (when applicable);
  - (c) Overhead or Indirect Costs - show rate, base and total amount as well as verification/allowability or rate changes (when applicable);
  - (d) Consultants - include the name, number of days or hours worked, a total amount per consultant and a total amount for this category;
  - (e) Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation, shown separately, and per diem costs. Other travel costs shall also be listed. A total amount for this category shall be provided;
  - (f) Subcontractors - include for each subcontractor, the same data that is being provided for the prime contractor. A total number for this category shall be provided.

- (g) Data Processing - include all non-labor costs, i.e., computer time, equipment purchase, lease or rental, data tapes, etc. A total amount for this category shall be provided.
  - (h) Other - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, equipment rental, duplication, etc.
  - (i) Equipment Cost - itemize and identify separately from material costs including reference to approval in all cases;
  - (j) G&A - show rate, base and total as well as verification/allowability of rate changes (when applicable); and
  - (k) Fee - show rate, base and total.
- (3) Payment shall be made by:

PSC Finance  
Parklawn Building, Room 16-23  
5600 Fishers Lane  
Rockville, Maryland 20857  
Telephone Number (301) 443-6766

## **G.5 INDIRECT COST RATES and FEE**

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), Allowable Cost and Payment, incorporated by reference in this contract, in Part II, Section I, the primary contact point responsible for negotiating provisional and/or final indirect cost rates is the cognizant contracting official as set forth in FAR Subpart 42.7 - Indirect Cost Rates.

Reimbursement will be limited to the rates and time periods covered by the negotiated agreements. The rates, if negotiated, are hereby incorporated without further action of the contracting officer.

## **G.6 ELECTRONIC FUNDS TRANSFER**

Pursuant to FAR 52.232-34, Payment by Electronic Funds Transfer - Other than Central Contractor Registration (MAY 1999), the Contractor shall designate a financial institution for receipt of electronic funds transfer payments. This designation shall be submitted, in writing, to the finance office designated in the contract.

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **H.1 RESTRICTIONS ON PUBLICATION AND DISSEMINATION OF MATERIAL DERIVED FROM WORK PERFORMED UNDER THIS CONTRACT**

Section 903(c) of the Public Health Service Act (PHS Act), 42 U.S.C. 299a-1, states in part that "No information, if the establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title, may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented...to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented...to its publication or release in other form."

To ensure compliance with these requirements and to fulfill the mandate of 923(b)(1) of the PHS Act, 42 U.S.C. 299c-2(b)(1), to assure that statistics developed with AHRQ support are of high quality, comprehensive, timely, and adequately analyzed, except as otherwise provided in this contract, the Agency for Healthcare Research and Quality (AHRQ) must, prior to dissemination by the contractor, review all reports, presentations, or other disclosures that contain information, statistics, analytical material, or any other material, which is based on or derived from work performed under this contract. Accordingly:

- (a) Except as provided in H.1(c), (e), and H.2(d), the contractor will not publish, have published, or otherwise disseminate any material resulting or derived from the work performed for AHRQ-funded research, except in accordance with the terms or conditions required by the Project Officer or until AHRQ has published the results of the research.
- (b) AHRQ will, within three months of the receipt of any proposed publication, presentation, or any other disclosure of materials derived from information collected or produced for a particular task order, use best effort to review the proposed report, presentation, or other text to assure that (1) identifiable information is being used for the purpose for which it was supplied; (2) the privacy of individuals supplying the information or described in it is not violated; and (3) the quality of statistical work meets the statutory standards cited above.
- (c) Except as provided in H.1(e), in the event no written conditions or approval are received from the Project Officer by the end of the three month period following submission of a request (that is accompanied by the proposed text) to publish a report or to make a presentation or other disclosure of material derived from work performed for AHRQ-funded research, the contractor may publish, present, or otherwise disclose this material subject to the restrictions of Section 903(c). However, the contractor must print prominently on the report or any portion of it which is released, or state prior to any oral or other disclosure of material derived from work performed under this contract, the following disclaimer:

**"THIS REPORT (*or other appropriate description of publication*) HAS NOT BEEN APPROVED BY THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY"**

- (d) Whether or not written approval of the Project Officer is received, the contractor must:

- print the following statement prominently on written reports or other forms of recorded data derived from work performed under this contract which is to be released; or
- preceding any presentation or other oral disclosure of such material make the following statement:

"IDENTIFIABLE INFORMATION ON WHICH THIS REPORT, PRESENTATION, OR OTHER FORM OF DISCLOSURE IS BASED, IS CONFIDENTIAL AND PROTECTED BY FEDERAL LAW, SECTION 903(c) OF THE PUBLIC HEALTH SERVICE ACT, 42 U.S.C. 299a-1(c). ANY IDENTIFIABLE INFORMATION THAT IS KNOWINGLY DISCLOSED IS DISCLOSED SOLELY FOR THE PURPOSE FOR WHICH IT HAS BEEN SUPPLIED. NO IDENTIFIABLE INFORMATION ABOUT ANY INDIVIDUAL SUPPLYING THE INFORMATION OR DESCRIBED IN IT WILL BE KNOWINGLY DISCLOSED EXCEPT WITH THE PRIOR CONSENT OF THAT INDIVIDUAL."

- (e) In cases where the Contracting Officer has given written notice that the Government intends to retain all rights in any particular data produced under this contract, the contractor shall have no right without prior written permission of the Contracting Officer to publish any of those data or analyses based on those data, depending on the scope of the Contracting Officer's notice.
- (f) Whenever data or analyses are to be developed by a subcontractor under this contract, the contractor must include the terms of H.1(a), (b), (c), (d) and (e) in the subcontract, without substantive alteration, and with a prohibition on the subcontractor engaging in further assignment of its obligations to the contractor. No clause may be included to diminish the Government's restriction on publication and dissemination of work or material derived from work performed under this contract.

**H.2 RIGHTS IN DATA -- SPECIAL WORKS (FAR Clause 52-227-17 June 1987) (DEVIATION)**

- (a) Definitions

"Computer software", as used in this clause, means computer programs, computer data bases, and documentation thereof.

"Data", as used in this clause, means recorded information, regardless of form or media on which it may be recorded (e.g., reports, tabulations, questionnaires, punch cards, data tapes, data files, tables, data processing and computer programs, graphic representations, sound recordings, form, work flow charts, equipment descriptions, and works of any similar nature). The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

"Form, fit, and function data", as used in this clause, means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, as well as data identifying source, size, configuration, mating, and attachment characteristics, functional characteristics, and performance requirements; except that for computer software it means data identifying source, functional characteristics, and performance requirements, but specifically excludes the source code, algorithm, process, formulae, and flow charts of the software.

"Unlimited rights", as used in this clause, means the right of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for Agency for Healthcare Research and Quality purposes, and to have or permit others to do so for Agency for Healthcare Research and Quality purposes.

(b) Allocation of Rights

(1) The Government shall have:

- (i) Unlimited rights in all data delivered under this contract, and in all data first produced in the performance of this contract, except as provided in paragraph (c) of this clause for copyright.
- (ii) The right to limit exercise of claim to copyright in data first produced in the performance of this contract, and to obtain assignment of copyright in such data, in accordance with subparagraph (c)(1) of this clause.
- (iii) The right to limit the release and use of certain data in accordance with paragraph (d) of this clause.

(2) The contractor shall have, to the extent permission is granted in accordance with subparagraph (c)(1) of this clause, the right to establish claim to copyright subsisting in data first produced in the performance of this contract.

(c) Copyright

(1) Data first produced in the performance of this contract

- (i) The contractor agrees not to assert, establish, or authorize other to assert or establish, any claim to copyright subsisting in any data first produced in the performance of the contract without prior written permission of the contracting officer. When claim to copyright is made, the contractor shall affix the appropriate copyright notice of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship (including contract number) to such data when delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office.



The contractor grants to the Government and the Government's licensees, a paid-up nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for Government purposes.

- (ii) If the Government desires to obtain copyright in data first produced in the performance of this contract and permission has not been granted as set forth in subdivision (c)(1)(i) of this clause, the contracting officer may direct the contractor to establish, or authorize the establishment of, claim to copyright in such data and to assign, or obtain the assignment of, such copyright to the Government or its designated assignee.

2) Data not first produced in the performance of this contract.

The contractor shall not, without prior written permission of the contracting officer, incorporate in the data delivered under this contract any data not first produced in the performance of this contract and which contain the copyright notice of 17 U.S.C. 401 or 402, unless the contractor identifies such data and grants to the government, or acquires on its behalf, a license of the same scope as set forth in subparagraph (c)(1) of this clause.

(d) Release and Use Restrictions

Except as otherwise specifically provided for in this contract (e.g., H.1(e)), the contractor shall not use for purposes other than the performance of this contract, nor shall the contractor release, reproduce, distribute, or publish any data first produced in the performance of this contract, nor authorize others to do so, without prior written permission of the Project Officer or until AHRQ has published the research for which the data were first produced.

(e) Indemnity

The contractor shall indemnify the Government and its officers, agents, and employees acting for the Government against any liability, included costs and expenses, incurred as the result of the violation of trade secrets, copyrights, or right of privacy or publicity, arising out of the creation, delivery, publication, or use of any data furnished under this contract; or any libelous or other unlawful matter contained in such data.

The provisions of this paragraph do not apply unless the Government provides notice to the contractor as soon as practicable of any claim or suit, affords the contractor an opportunity under applicable laws, rules, or regulations to participate in the defense thereof, and obtains the contractor's consent to the settlement of any suit or claim other than as required by final decree of a court of competent jurisdiction. Further, these provisions do not apply to material furnished to the contractor by the Government and incorporated in data to which this clause applies, nor in cases where Government officers, agents, and employees are solely at fault.

- (f) The contractor must release all required deliverables under this contract solely in accordance with the reporting requirements of this contract.
- (g) In accordance with the **Federal Register** (Vol. 57, No. 167, August 27, 1992, pp:38845-38848) the contractor is to provide for secure and confidential storage, retrieval access, maintenance, and disposition of data and other information used in the work performed under the contract.
- (h) Whenever any data is to be developed by a subcontractor under this contract, the contractor must include the terms of H.1(a), (b), (c), (d), (e), (f) and (g) in the subcontract, without substantive alteration, and with a prohibition on the subcontractor engaging in further assignment of its obligations to the contractor, and no clause may be included to diminish the Government' rights in those data.

### **H.3 DEBARMENT**

Violation of the special provisions of this contract entitled **RESTRICTIONS ON PUBLICATION AND DISSEMINATION OF MATERIAL DERIVED FROM WORK PERFORMED UNDER THIS CONTRACT, and RIGHTS IN DATA - SPECIAL WORKS** will be viewed as a serious violation of the terms of this contract as the requirements in this provision reflect AHRQ statutory obligations and responsibilities. Such violations, as well as other violations, of the contract terms which are deemed serious, could result in the initiation of debarment proceedings in accordance with the Federal Acquisition Regulations and the Department of Health and Human Services implementing regulations.

### **H.4 SUBCONTRACTS**

The contractor must include in any subcontracts executed or used to provide the support specified in this contract the terms of requirements H.1, H.2 and H.3. These requirements are to be included without substantive alteration, and no clause may be included to diminish these requirements.

Award of any subcontract is subject to the written approval of the Contracting Officer upon review of the supporting documentation as required by FAR Clause 52.215-12, Subcontractor Cost or Pricing Data, of the General Clauses incorporated into this contract. A copy of the signed subcontract shall be provided to the Contracting Officer.

### **H.5 LATE PAYMENTS TO THE GOVERNMENT**

Late payment of debts owed the Government by the Contractor, arising from whatever cause, under this contract/order shall bear interest at a rate or rates to be established in accordance with the Treasury Fiscal Requirements Manual. For purposes of this provision, late payments are defined as payments received by the Government more than 30 days after the Contractor has been notified in writing by the Contracting Officer of:

- a. The basis of indebtedness.

- b. The amount due.
- c. The fact that interest will be applied if payment is not received within 30 days from the date of mailing of the notice.
- d. The approximate interest rate that will be charged.

## **H.6 PRIVACY ACT**

The Privacy Act clauses cited in Section I (FAR 52.224-1 and 52.224-2) are applicable to the consultant records kept by the Contractor for the Agency for Healthcare Research and Quality.

You are hereby notified that the Contractor and its employees are subject to criminal penalties for violations of the Act (5 U.S.C. 552a(i)) to the same extent as employees of the Department. The Contractor shall assure that each Contractor employee is aware that he/she can be subjected to criminal penalties for violations of the Act. Disposition instructions: Records are to be destroyed after contract closeout is completed and final payment is made and in accordance with IRS regulations.

## **H.7 PRO-CHILDREN ACT of 1994**

The Pro-Children Act of 1994, P.L. 103-227, imposes restrictions on smoking where certain federally funded childrens' services are provided. P.L. 103-227 states in pertinent part:

“PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, P.L. 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.”

## **H.8 SUPPLIES**

The contractor shall maintain a list of all items, both expendable and non-expendable, which are unique or in excess of regular office needs normally captured in an indirect cost pool. These items are considered Government property and are cost of goods inventory deliverable to the Government at the end of the contract.

## **H.9 GOVERNMENT-FURNISHED MATERIALS**

Unless otherwise stated in a specific task order, the contractor will furnish all the necessary personnel, materials, data, facilities, or services or otherwise all things necessary for or incident to the performance of the tasks stated in an individual task order.

## **H.10 SALARY CAP GUIDE NOTICE**

Pursuant to P.L. 107-116, no Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the direct salary rate for Executive Level I of the Federal Executive Pay Scale. That rate is

\$166,700 per year for the period of January 1, 2002 through December 31, 2002. Direct salary is exclusive of overhead, fringe benefits, and general and administrative expenses. The salary limit also applies to individuals proposed under subcontracts. If this is a multi-year contract, it may be subject to unilateral modifications by the Government if any salary rate ceilings are established in future DHHS appropriation acts. P.L. 107-116 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse and Mental Health Services Administration shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level I."

Contractors shall absorb that portion of an employee's salary (plus the dollar amount for fringe benefits and indirect costs associated with the excess) that exceeds a rate of \$166,700 a year.

**PART II - CONTRACT CLAUSES (5/02-DCM)**  
**(FAC 2001-07)**  
**SECTION I**  
**CONTRACT CLAUSES**  
**GENERAL CLAUSES FOR A**  
**COST REIMBURSEMENT CONTRACT**

**I.1 CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be assessed electronically at this address:  
<http://www.arnet.gov/far/>

**FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES**

<b>FAR Clause No.</b>	<b>Title and Date</b>
52.203-3	Gratuities (APRIL 1984)
52.203-5	Covenant Against Contingent Fee (APRIL 1984)
52.203-6	Restrictions on Subcontractor Sales to the Government (July 1995)
52.203-7	Anti-Kickback Procedures (JULY 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (JAN 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (JAN 1997)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (JUN 1997)
52.204-4	Printing/Copying Double-Sided on Recycled Paper (AUG 2000)
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (JULY 1995)
52.215-2	Audit and Records - Negotiation (JUNE 1999)
52.215-8	Order of Precedence-Uniform Contract Format (Oct 1997)
52.215-10	Price Reduction for Defective Cost or Pricing Data (OCT 1997) (applicable to contract actions over \$500,000)

52.215-12	Subcontractor Cost or Pricing Data (OCT 1997) (applicable to contract actions over \$500,000)
52.215-15	Pension Adjustments and Asset Reversions (DEC 1998)
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits Other Than Pensions (PRB) (OCT 1997)
52.215-19	Notification of Ownership Changes (OCT 1997)
52.216-7	Allowable Cost and Payment (FEB 2002)
52.216-8	Fixed Fee (MARCH 1997)
52.217-2	Cancellation Under Multiyear Contracts (OCT 1997)
52.219-6	Notice of Total Small Business Set-Aside (JULY 1996)
52.219-8	Utilization of Small Business Concerns (OCT 2000)
52.219-14	Limitations on Subcontracting (DEC 1996)
52.222-2	Payment for Overtime Premiums (JULY 1990). The amount in paragraph (a) is "zero" unless different amount is separately stated elsewhere in contract.
52.222-3	Convict Labor (AUG 1996)
52.222-26	Equal Opportunity (APR 2002)
52.222-35	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (APR 1998)
52.222-36	Affirmative Action for Workers With Disabilities (JUNE 1998)
52.222-37	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era (DEC 2001)
52.223-6	Drug Free Workplace (MAY 2001)
52.223-14	Toxic Chemical Release Reporting (OCT 2000)
52.224-1	Privacy Act Notification (APRIL 1984)
52.224-2	Privacy Act (APRIL 1984)
52.225-1	Buy American Act - Supplies (MAY 2002)
52.225-13	Restrictions on Certain Foreign Purchases (JULY 2000)
52.227-1	Authorization and Consent (JULY 1995)
52.227-2	Notice and Assistance Regarding Patent and Copy-Right Infringement (AUG 1996)
52.227-3	Patent Indemnity (APRIL 1984)
52.227-14	Rights in Data - General (JUNE 1987)

52.228-7	Insurance-Liability to Third Persons (MAR 1996)
52.230-2	Cost Accounting Standards (APR 1998)
52.230-3	Disclosure and Consistency of Cost Accounting Practices (APR 1998)
52.230-6	Administration of Cost Accounting Standards (NOV 1999)
52.232-9	Limitation on Withholding of Payments (APRIL 1984)
52.232-17	Interest (JUNE 1996)
52.232-20	Limitation of Cost (APR 1984)
52.232-22	Limitation of Funds (APR 1984) (This clause supersedes the Limitation of Cost clause found in the General Clauses of this contract.)
52.232-23	Assignment of Claims (JAN 1986)
52.232-25	Prompt Payment (FEB 2002)
52.232-34	Payment by Electronic Funds Transfer- Other than Central Contractor Registration (MAY 1999)
52.233-1	Disputes (DEC 1998)
52.233-3	Protest After Award (AUG 1996) Alternate I (JUNE 1985)
52.237-10	Identification of Uncompensated Overtime (Oct 1997)
52.242-1	Notice of Intent to Disallow Costs (APRIL 1984)
52.242-3	Penalties for Unallowable Costs (MAY 2001)
52.242-4	Certification of Final Indirect Costs (Jan 1997)
52.242-13	Bankruptcy (JULY 1995)
52.243-2	Changes - Cost Reimbursement (AUG 1987) - Alternate II (APRIL 1984)
52.244-2	Subcontracts (AUGUST 1998)
52.244-5	Competition in Subcontracting (DEC 1996)
52.245-5	Government Property (Cost Reimbursement, Time-and-Material, or Labor-Hour Contract (JAN 1986)
52.246-5	Inspection of Services-Cost Reimbursement (APRIL 1984)
52.246-23	Limitation of Liability-(FEB 1997)
52.248-1	Value Engineering (FEB 2000)
52.249-6	Termination (Cost-Reimbursement) (SEP 1996)
52.249-14	Excusable Delays (APRIL 1984)
52.251-1	Government Supply Sources (APRIL 1984)

52.253-1

Computer Generated Forms (JAN 1991)

**II. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION  
REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES**

**HHSAR**

**Clause No.**

**Title and Date**

352.202-1

Definitions (JAN 2001)  
Alternate I (APRIL 1984)

352.224-70

Confidentiality of Information (APRIL  
1984)

352.228-7

Insurance - Liability to Third Persons (DEC  
1991)

352.232-9

Withholding of Contract Payments (APRIL  
1984)

352.233-70

Litigation and Claims (APR 1984)

352.242-71

Final Decisions on Audit Findings (APRIL  
1984)

352.270-1

Accessibility of Meetings, Conferences, and  
Seminars to Persons With Disabilities  
(APRIL 1984)

352.270-6

Publication and Publicity (JUL 1991)

352.270-7

Paperwork Reduction Act (APR 1984)

The following clauses are applicable to this contract and are provided in full text:

**I.2 KEY PERSONNEL (APRIL 1984)(HSAR 352.270-5)**

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

(End of clause)

**PART III- LIST OF DOCUMENTS, EXHIBITS AND ATTACHMENTS**



## SECTION J - LIST OF ATTACHMENTS

<u>Attachment</u>	<u>Pages</u>
1. List of Reference Materials	1
2. List of Resources for Accessibility and Privacy Act Guidance	2
3. Implementation Planning Study for the Integration of Medical Event Reporting Input and Data Structure for Reporting to AHRQ, CDC, CMS, and FDA - Volume I - Technical Report	138
4. Implementation Planning Study for the Integration of Medical Event Reporting Input and Data Structure for Reporting to AHRQ, CDC, CMS, and FDA - Volume II - Appendixes	242
5. Barach P., Small SD Reporting and Preventing Medical Mishaps: Lessons from Non-medical Near Miss Reporting Systems. <i>BMJ</i> 2000; 320:759-763.	5
6. Battles JB, Kaplan HS, van der Schaaf TW, Shea CE. The attributes of medical event reporting systems. <i>Archives of Pathology Laboratory Medicine</i> ; 1998; 122:3:132-138.	8
7. Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. <i>Acad Med</i> 2001;76:2:125-133.	9
8. Kaplan HS, Battles JB, van der Schaaf TW, Shea CE, Mercer SQ. Identification and classification of the causes of events in transfusion medicine. <i>Transfusion</i> . 1998 38: 1071-1081.	11
9. Past Performance Questionnaire and Contractor Performance Form	5
10. SF LLL-A, Disclosure of Lobbying Activities	3

**NOTE: ALL ATTACHMENTS ARE LOCATED AT THE END OF THIS REQUEST FOR PROPOSAL**

**(FAC 2001-7)**

**PART IV. REPRESENTATIONS AND INSTRUCTIONS**  
**SECTION K**  
**REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

K.1	HHSAR 315.204-5	Representations and Instructions
K.2	FAR 52.203-2	Certification of Independent Price Determination (APRIL 1985)
K.3	FAR 52.203-11	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (APR 1991)
K.4	FAR 52.204-3	Taxpayer Identification (OCT 1998)
K.5	FAR 52.204-5	Women-Owned Business Other than Small Business (May 1999)
K.6	FAR 52.209-5	Certification Regarding Debarment, Suspension, Proposed Debarment, and Other Responsibility Matters (DEC 2001)
K.7	FAR 52.215-6	Place of Performance (OCT 1997)
K.8	FAR 52.219-1	Small Business Program Representations (APRIL 2002)
K.9	FAR 52.222-21	Prohibition of Segregated Facilities (FEB 1999)
K.10	FAR 52.222-22	Previous Contracts and Compliance Reports (FEB 1999)
K.11	FAR 52.222-25	Affirmative Action Compliance (APRIL 1984)
K.12	FAR 52.223-13	Certification of Toxic Chemical Release Reporting (OCT 2000)
K.13	FAR 52.225-2	Buy American Act Certificate (MAY 2002)
K.14	FAR 52.226-2	Historically Black College or University and Minority Institution Representation (MAY 2001)
K.15	FAR 52.227-15	Representation of Limited Rights Data and Restricted Computer Software (MAY 1999)
K.16	FAR 52.230-1	Cost Accounting Standards Notice and Certification (JUNE 2000)
K.17	FAR 15.406-2	Certificate of Current Cost and Pricing Data
K.18	P.L. 103-227	Certification Regarding Environmental Tobacco Smoke

**K.1 REPRESENTATIONS AND INSTRUCTIONS**

(a) Section K, Representations, certifications, and other statements of offerors.

(1) This section shall begin with the following and continue with the applicable representations and certifications:

TO BE COMPLETED BY THE OFFEROR: (The Representations and Certifications must be executed by an individual authorized to bind the Offeror.) The Offeror makes the following Representations and Certifications as part of its proposal. (Check or complete all appropriate boxes or blanks on the following pages.)

\_\_\_\_\_  
(Name of Offeror)

\_\_\_\_\_  
(RFP No.)

\_\_\_\_\_  
(Signature of Authorized Individual)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Typed Name of Authorized Individual)

NOTE: The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

**K.2 CERTIFICATE OF INDEPENDENT PRICE DETERMINATION (APR 1985) (FAR 52.203-2)**

(a) The offeror certifies that--

- (1) The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to (i) those prices, (ii) the intention to submit an offer, or (iii) the methods or factors used to calculate the prices offered;
- (2) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award (in the case of a negotiated solicitation) unless otherwise required by law; and
- (3) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory--

- (1) Is the person in the offeror's organization responsible for determining the prices being offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above; or
- (2) (i) Has been authorized, in writing, to act as an agent for the following principals in certifying that those principals have not participated, and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above.

---



---



---



---



---



---

[Insert full name of person(s) in the offeror's organization responsible for determining the prices offered in the bid or proposal, and the title of his or her position in the offeror's organization];

- (ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) above have not participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above; and
- (iii) As an agent, has not personally participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above.
- (c) If the offeror deletes or modifies subparagraph (a)(2) above, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure.

(End of provision)

**K.3 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (APR 1991) (FAR 52.203-11)**

- (a) The definitions and prohibitions contained in the clause at FAR 52.203-12, Limitation on Payments to Influence Certain Federal Transactions, included in this solicitation, are hereby incorporated by reference in paragraph (b) of this certification.
- (b) The offeror, by signing its offer, hereby certifies to the best of his or her knowledge and belief that on or after December 23, 1989,--
  - (1) No Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal

loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement;

- (2) If any funds other than Federal appropriated funds (including profit or fee received under a covered Federal transaction) have been paid, or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with this solicitation, the offeror shall complete and submit, with its offer, OMB Standard Form-LLL, Disclosure of Lobbying Activities, to the Contracting Officer; and
  - (3) He or she will include the language of this certification in all subcontract awards at any tier and require that all recipients of subcontract awards in excess of \$100,000 shall certify and disclose accordingly.
- (c) Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by section 1352, title 31, United States Code. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure form to be filed or amended by this provision, shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

(End of provision)

#### **K.4 TAXPAYER IDENTIFICATION (FAR 52.204-3) (OCT 1998)**

- (a) Definitions:

"Common parent," as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

"Taxpayer Identification Number (TIN)," as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may either be a Social Security Number or an Employer Identification Number.

- (b) All offerors are required to submit the information required in paragraph (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M and implementing regulations issued by the IRS. If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.
- (c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C.

7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(d) Taxpayer Identification Number (TIN).

TIN: \_\_\_\_\_

TIN has been applied for.

TIN is not required because:

- Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have an income effectively connected with the conduct of a trade or business in the United States (U.S.) and does not have an office or place of business or a fiscal paying agent in the U.S.;
- Offeror is an agency or instrumentality of a foreign government;
- Offeror is an agency or instrumentality of a Federal, state, or local government.

(e) Type of organization.

Sole proprietorship;

Partnership;

Corporate entity (not tax-exempt);

Corporate entity (tax-exempt);

Government entity (Federal, State, or local);

Foreign government;

International organization per 26 CFR 1.6049-4;

Other \_\_\_\_\_.

(f) Common Parent.

Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this clause.

Name and TIN of common parent:

Name \_\_\_\_\_

TIN \_\_\_\_\_

(End of provision)

#### **K.5 WOMEN-OWNED BUSINESS(Other Than Small Business) (MAY 1999) (FAR 52.204-5)**

(a) Definition. "Women-owned business concern," as used in this provision, means a concern that is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

- (b) Representation. *[Complete only if the offeror is a women-owned business concern and has not represented itself as a small business concern in paragraph (b)(1) of FAR 52.219-1, Small Business Program Representations, of this solicitation.]* The offeror represents that it is  is not  a women-owned business concern.

(End of Provision)

**K.6 CERTIFICATION REGARDING DEBARMENT, SUSPENSION, PROPOSED DEBARMENT, AND OTHER RESPONSIBILITY MATTERS (DEC 2001)(FAR 52.209-5)**

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that—

(i) The Offeror and/or any of its Principals—

- (A) Are  are not  presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;
- (B) Have  have not , within a three-year period preceding this offer, been convicted of or had a civil judgement rendered against them for: commission of fraud of a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion or receiving stolen property; and
- (C) Are  are not  presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in subdivision (a)(1)(i)(B) of this provision.

(ii) The Offeror has  has not , within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principals," for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment, and similar positions).

THIS CERTIFICATION CONCERNS A MATTER WITHIN THE JURISDICTION OF AN AGENCY OF THE UNITED STATES AND THE MAKING OF A FALSE, FICTITIOUS, OR FRAUDULENT CERTIFICATION MAY RENDER THE MAKE SUBJECT TO PROSECUTION UNDER SECTION 1001, TITLE 18, UNITED STATES CODE.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

- (c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.
- (d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
- (e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

**K.7 PLACE OF PERFORMANCE(OCT 1997) (FAR 52.215-6)**

- (a) The offeror or respondent, in the performance of any contract resulting from this solicitation, [ ] intends, [ ] does not intend (check applicable box) to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.
- (b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces required information:

Place of Performance (Street  
Address, City, County State,  
Zip Code)

Name and Address of Owner  
and Operator of the Plant  
or Facility if Other than Offeror or  
respondent

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(End of provision)



**K.8 SMALL BUSINESS PROGRAM REPRESENTATIONS(APR 2002) (FAR 52.219-1)**

- (a)
  - (1) The North American Industry Classification System (NAICS) code for this acquisition is 541542.
  - (2) The small business size standard is \$18.0 million.
  - (3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is (see above) employees.
  
- (b) Representations.
  - (1) The offeror represents as part of its offer that it  is,  is not a small business concern.
  - (2) [Complete only if offeror represented itself as a small business concern in block (b)(1) of this provision.]  
The offeror represents, for general statistical purposes that it  is  is not a small disadvantaged business concern as defined in 13 CFR 124.1002.
  - (3) [Complete only if offeror represented itself as a small business concern in block (b)(1) of this section.]  
The offeror represents as part of its offer that it  is  is not a women-owned small business concern.
  - (4) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.]  
The offeror represents as part of its offer that it  is,  is not a veteran-owned small business concern.
  - (5) [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(4) of this provision.]  
The offeror represents as part of its offer that it  is,  is not a service-disabled veteran-owned small business concern.
  - (6) [Complete only if offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, as part of its offer, that -
    - (i) It  is,  is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration (SBA), and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the SBA in accordance with 13 CFR part 126; and
    - (ii) It  is,  is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(6)(i) of this provision is accurate for the HUBZone small business concern or concerns

that are participating in the joint venture. (The offeror shall enter the name and names of the HUBZone small business concern or concerns that are participating in the joint venture: \_\_\_\_\_.) Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(c) Definitions. As used in this provision -

**Service-disabled veteran-owned small business concern-**

(1) Means a small business concern -

- (i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and
- (ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) **Service-disabled veteran** means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service connected, as defined in 38 U.S.C. 101(16).

**Small business concern**, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

**Veteran-owned small business concern**, means a small business concern -

- (1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and
- (2) The management and daily business operations of which are controlled by one or more veterans.

**Women-owned small business concern**, as used in this provision, means a small business concern –

- (1) That is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

- (2) Whose management and daily business operations are controlled by one or more women.
- (d) Notice.
  - (1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.
  - (2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, HUBZone small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to sections 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall
    - (i) be punished by imposition of a fine, imprisonment, or both;
    - (ii) be subject to administrative remedies, including suspension and debarment; and
    - (iii) be ineligible for participation in programs conducted under the authority of the Act.

(End of Provision)

**K.9 PROHIBITION OF SEGREGATED FACILITIES (FEB 1999) (FAR 52.222-21)**

- (a) "Segregated facilities," as used in this clause, means any waiting rooms, work areas, rest rooms and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees, that are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin because of written or oral policies or employee custom. The term does not include separate or single-user rest rooms or necessary dressing or sleeping areas provided to assure privacy between the sexes.
- (b) The Contractor agrees that it does not and will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not and will not permit its employees to perform their services at any location under its control where segregated facilities are maintained. The Contractor agrees that a breach of this clause is a violation of the Equal Opportunity clause in this contract.
- (c) The Contractor shall include this clause in every subcontract and purchase order that is subject to the Equal Opportunity clause of this contract.

(End of Clause)

**K.10 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS(FEB 1999) (FAR 52.222-22)**

The offeror represents that--

- (a) It [ ] has, [ ] has not participated in a previous contract or subcontract subject either to the Equal Opportunity clause of this solicitation;
- (b) It [ ] has, [ ] has not filed all required compliance reports; and
- (c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

(End of provision)

**K.11 AFFIRMATIVE ACTION COMPLIANCE(APR 1984) (FAR 52.222-25)**

The offeror represents that--

- (a) It [ ] has developed and has on file, [ ] has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (4) CFR 60-1 and 60-2,

or

- (b) It [ ] has not previously had contracts subject to the written affirmative action programs requirements of the rules and regulations of the Secretary of Labor.

(End of provision)

**K.12 CERTIFICATION OF TOXIC CHEMICAL RELEASE REPORTING (OCT 2000) (FAR 52.223-13)**

- (a) Submission of this certification is a prerequisite for making or entering into this contract imposed by Executive Order 12969, August 8, 1995.
- (b) By signing this offer, the offeror certifies that -
  - (1) As the owner or operator of facilities that will be used in the performance of this contract that are subject to the filing and reporting requirements described in section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11023) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13106), the offeror will file and continue to file for such facilities for the life of the contract the Toxic Chemical Release Inventory Form (Form R) as described in sections 313(a) and (g) of EPCRA and section 6607 of PPA; or

- (2) None of its owned or operated facilities to be used in the performance of this contract is subject to the Form R filing and reporting requirements because each such facility is exempt for at least one of the following reasons: (Check each block that is applicable.)
- (i)The facility does not manufacture, process, or otherwise use any toxic chemicals listed under section 313(c) of EPCRA, 42 U.S.C. 11023(c);
- (ii)The facility does not have 10 or more full-time employees as specified in section 313(b)(1)(A) of EPCRA, 42 U.S.C. 11023(b)(1)(A).
- (iii)The facility does not meet the reporting thresholds of toxic chemicals established under section 313(f) of EPCRA, 42 U.S.C. 11023(f) (including the alternate thresholds at 40 CFR 372.27, provided an appropriate certification form has been filed with EPA).
- (iv)The facility does not fall within Standard Industrial Classification Code (SIC) major groups 20 through 39 or their corresponding North American Industry Classification System (NAICS) sectors 31 through 33; or
- (v)The facility is not located within any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, the Northern Mariana Islands, or any other territory or possession over which the United States has jurisdiction.

**K.13 BUY AMERICAN ACT CERTIFICATE (MAY 2002) (FAR 52.225-2)**

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a domestic end product as defined in the clause of this solicitation entitled "Buy American Act--Supplies", and that the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(b) Foreign End Products

Line Item No.	Country of Origin
---------------	-------------------


(List as necessary)

(c) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition

(End of provision)

**K.14 HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION (MAY 2001)(FAR 52.226-2)**

- (a) Definitions. As used in this provision-“Historically Black College or University” means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2. For the Department of Defense, the National Aeronautics and Space Administration , and the Coast Guard, the term also includes any nonprofit research institution that was an integral part of such a college or university before November 14, 1986.

“Minority Institution” means an institution of higher education meeting the requirements of Section 1046(3) of the Higher Education Act of 1965 (20 U.S.C. 1076k including a Hispanic-serving institution of higher education as defined in Section 316(b)(1) of the Act (20 U.S.C. 1101(a)).

- (b) Representation. The offeror represents that it-  
\_\_\_ is \_\_\_ is not a Historically Black College or University;  
\_\_\_ is \_\_\_ is not a Minority Institution

(End of Provision)

**K.15 REPRESENTATION OF LIMITED RIGHTS DATA AND RESTRICTED COMPUTER SOFTWARE (MAY 1999)**

- (a) This solicitation sets forth the work to be performed if a contract award results, and the Government’s known delivery requirements for data (as defined in FAR 27.401) Any resulting contract may also provide the Government the option to order additional data under the Additional Data Requirements clause at 52.227-16 of the FAR, if included in the contract. Any data delivered under the resulting contract will be subject to the Rights in Data - General clause at 52.227-14 that is to be included in this contract. Under the latter clause, a Contractor may withhold from delivery data that qualify as limited rights data or restricted computer software, and deliver form, fit an function data in lieu thereof. The latter clause also may be used with its Alternates II and/or III to obtain delivery of limited rights or restricted computer software, marked with limited rights or restricted rights notices, as appropriate. In addition, use of Alternate V with this latter clause provides the Government the right to inspect such data at the Contractor’s facility.
- (b) As an aid in determining the Government’s need to include Alternate II or Alternate III in the clause at 52.227-14, Rights in Data - General, the offeror shall complete paragraph (c) of this provision to either state that none of the data qualify as limited rights data or restricted computer software, or identify, to the extent feasible, which of the data qualifies as limited rights data or restricted computer software. Any identification of limited rights data or restricted computer software in the offeror’s response is not determinative of the status of such data should a contract be awarded to the offeror.
- (c) The offeror has reviewed the requirements for the delivery of data or software and states [offeror check appropriate block] -

[ ] None of the data proposed for fulfilling such requirements qualifies as limited rights data or restricted computer software.

[ ] Data proposed for fulfilling such requirements qualify as limited rights data or restricted computer software and are identified as follows:

---

---

---

---

---

---

---

---

**K.16 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (JUNE 2000)  
(FAR 52.230-1)**

NOTE: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS-coverage pursuant to 48CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

**I. Disclosure Statement - Cost Accounting Practices and Certification**

- (a) Any contract in excess of \$500,000 resulting from this solicitation, will be subject to the requirements of the Cost Accounting Standards Board (48 CFR, Chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.
- (b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

Caution: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) Certificate of Concurrent Submission of Disclosure Statement. The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows: (i) original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity, as applicable, and (ii) one copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the loose-leaf version of the Federal Acquisition Regulation.)

Date of Disclosure Statement: \_\_\_\_\_

Name and Address of Cognizant ACO or Federal official where filed:  
\_\_\_\_\_  
\_\_\_\_\_

The offeror further certifies that practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) Certificate of Previously Submitted Disclosure Statement.

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: \_\_\_\_\_

Name and Address of Cognizant ACO or Federal official where filed:  
\_\_\_\_\_  
\_\_\_\_\_

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) Certificate of Monetary Exemption.

The offeror hereby certifies that the offeror together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS



totaling more than \$25 million in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) Certificate of Interim Exemption.

The offeror hereby certifies that (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and (ii) in accordance with 48 CFR, Subpart 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a review certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or

(c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

Caution: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of \$25 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

## II. Cost Accounting Standards - Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR, Subpart 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR, Subpart 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than \$25 million in awards of CAS-covered prime contracts and subcontracts or the offeror did not receive a single CAS-covered award exceeding \$1 million. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

Caution: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of \$25 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of \$25 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

Yes  No

(End of Provision)

**ALTERNATE I (APR 1996)**

(5) Certificate of Disclosure Statement Due Date by Educational Institution.

If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903.202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that (check one and complete):

(a) A Disclosure Statement filing Due Date of has been established with the cognizant Federal agency.

(b) The Disclosure Statement will be submitted within the six month period ending months after receipt of this award.

Name and Address of cognizant ACO or Federal Official where Disclosure Statement is to be filed:

(END OF ALTERNATE I)

**K.17 CERTIFICATE OF CURRENT COST OR PRICING DATA (FAR 15.406-2)**

**CERTIFICATE OF CURRENT COST OR PRICING DATA**

When cost or pricing data are required, the contracting officer shall require the contractor to execute a Certificate of Current Cost or Pricing Data using the format in this paragraph, and shall include the executed certificate in the contract file.

This is to certify that, to the best of my knowledge and belief, the cost or pricing data (as defined in Section 15.401 of the Federal Acquisition Regulation(FAR) and required under FAR

subsection 15.403-4) submitted, either actually or by specific identification, in writing, to the contracting officer or the contracting officer's representative in support of \_\_\_\_\_\* are accurate, complete, and current as of \_\_\_\_\_\*\*.

This certification includes the cost or pricing data supporting any advance agreements and forward pricing rate agreements between the offeror and the Government that are part of the proposal.

FIRM \_\_\_\_\_

NAME \_\_\_\_\_ Signature\_\_\_\_\_

TITLE \_\_\_\_\_

DATE OF EXECUTION\*\*\* \_\_\_\_\_

\* Identify the proposal, request for price adjustment, or other submission involved, giving the appropriate identifying number (e.g., Request for Proposal number).

\*\* Insert the day, month, and year when price negotiations were concluded and price agreement was reached or, if applicable, an earlier date agreed upon between the parties that is as close as practicable to the date of agreement on price.

\*\*\* Insert the day, month, and year of signing, which should be as close as practicable to the date when the price negotiations were concluded and the contract price agreed to.

End of Certificate

## **K.18 ENVIRONMENTAL TOBACCO SMOKE**

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

### **CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE**

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole

source of applicable Federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By signing this certification, the offeror/contractor certifies that the submitted organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

Organization: \_\_\_\_\_

Signature \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_

## **SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS**

### **L.1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998) (FAR 52.252-1)**

This solicitation incorporates the following solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the contracting officer will make the full text available. Also, the full text of a clause may be assessed electronically at this address: <http://www.arnet.gov/far/>

- a. Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Solicitation Provisions
  - (1) 52.215-16 Facilities Capital Cost of Money (OCT 1997)
  - (2) 52.215-20 Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data (OCT 1997)

### **L.2 DATA UNIVERSAL NUMBERING (DUNS) NUMBER (JUNE 1999) (FAR 52.204-6)**

- (a) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" followed by the DUNS number that identifies the offeror's name and address exactly as stated in the offer. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services.
- (b) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one. A DUNS number will be provided immediately by telephone at no charge to the offeror. For information on obtaining a DUNS number, the offeror, if located within the United States, should call Dun and Bradstreet at 1-800-333-0505. The offeror should be prepared to provide the following information:
  - (1) Company name.
  - (2) Company address.
  - (3) Company telephone number.
  - (4) Line of business.
  - (5) Chief executive officer/key manager.
  - (6) Date the company was started.
  - (7) Number of people employed by the company.
  - (8) Company affiliation.
- (c) Offerors located outside the United States may obtain the location and phone number of the local Dun and Bradstreet Information Services office from the Internet home page at <http://www.customerservice@dnb.com/>. If an offeror is unable to locate a local service center, it may send an e-mail to Dun and Bradstreet at [globalinfo@mail.dnb.com](mailto:globalinfo@mail.dnb.com).

(End of provision)

### **L.3 INSTRUCTIONS TO OFFERORS - COMPETITIVE ACQUISITION (MAY 2001)**

**ALTERNATE I (OCT 1997)(FAR 52.215-1)**

(a) Definitions. As used in this provision –

“Discussions” are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer’s discretion, result in the offeror being allowed to revise its proposal.

“In writing,” “writing,” or “written” means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

“Proposal modification” is a change made to a proposal before the solicitation’s closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

“Proposal revision” is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

“Time,” if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday or legal holiday, then the period shall include the next working day.

(b) Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals.

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show—

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any

or all items upon which prices are offered at the price set opposite each item;

- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submissions, modification, revision, and withdrawal of proposals.

- (i) Offerors are responsible for submitting proposals, and any modification or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

- (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and -

- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

- (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

- (3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
  - (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
  - (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, "Facsimile Proposals." Proposals may be withdrawn in person by an offeror or an authorized representative, if the representative's identity is made known and the representative signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
  - (5) Offerors shall submit proposals submitted in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
  - (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
  - (7) Offers may submit revised proposals only if requested or allowed by the Contracting Officer.
  - (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).



(e) Restriction on disclosure and use of data. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall —

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of—or in connection with—the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government’s right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) Contract award.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government’s interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror’s initial proposal should contain the offeror’s best terms from a price and technical standpoint.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in postaward debriefings to other offerors:
  - (i) The overall evaluated cost or price and technical rating of the successful offeror.
  - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
  - (iii) A summary of the rationale for award; and
  - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of provision)

#### **L.4 TYPE OF CONTRACT (APRIL 1984)(FAR 52.216-1)**

The Government contemplates award of a cost reimbursement type contract resulting from this solicitation.

It is anticipated that one (1) award will be made from this solicitation and that the award will be made on/about September 30, 2002.

**L.5 SERVICE OF PROTEST(AUG 1996)(FAR 52.233-2)**

- (a) Protests, as defined in Section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO) shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Director, Division of Contracts Management  
Agency for Healthcare Research and Quality  
2101 East Jefferson Street, Suite 502  
Rockville, Maryland 20852

- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

**L.6 POINT OF CONTACT FOR TECHNICAL INQUIRIES**

The technical contact for additional information and answering inquiries is the Contracting Officer.

All questions regarding this solicitation shall be in writing and received by the Contracting Officer no later than **July 15, 2002**. **Due to the time constraint of awarding this contract by the end of our fiscal year on September 30, 2002, no extensions will be issued on the due date of the proposal which is August 9, 2002.** Answers to questions shall be posted in an amendment on AHRQ's web site <http://www.ahrq.gov> below the solicitation (see Funding Opportunities).

Mail inquiries to:

Agency for Healthcare Research and Quality  
Division of Contracts Management  
2101 East Jefferson Street, Suite 502  
Rockville, MD 20852  
Attention: Darryl Grant, Contracting Officer

Fax: (301) 443-7523

**L.7 REFERENCE MATERIALS**

Attached to this solicitation is a list of reference material applicable to this acquisition (see **Attachment 1**). Some of the references have been included as attachments. Additional references shall not be provided since they are readily accessible.

## L.8 GENERAL INSTRUCTIONS

### Introduction

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions:

- a. Contract Type and General Provisions: It is contemplated that a cost-type contract will be awarded. In addition to the special provisions of this request for proposal (RFP), any resultant contract shall include the general clauses applicable to the selected offeror's organization and type of contract awarded. Any additional clauses required by Public Law, Executive Order, or procurement regulations, in effect at the time of execution of the proposed contract, will be included.
- b. Authorized Official and Submission of Proposal: The proposal shall be signed by an official authorized to bind your (the offeror's) organization. Your proposal shall be submitted in the number of copies, to the address, and marked as indicated in the cover letter of this solicitation. Proposals will be typewritten, reproduced on letter sized paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:
  - I. COVER PAGE: Include RFP title, number, name of organization, author(s) of technical proposal, and indicate whether the proposal is an original or a copy.
  - II. TECHNICAL PROPOSAL: See Technical Proposal Instructions for recommended format (L.9).
  - III. PAST PERFORMANCE INFORMATION: See Past Performance Information Instructions for format (L.10)
  - IV. BUSINESS PROPOSAL: See Business Proposal Instructions for recommended format (L.11).
- c. Separation of Technical, Past Performance Information, and Business Proposal: The proposal shall be in 3 parts:
  - (1) Technical Proposal; (2) Past Performance Information; and (3) Business Proposal. Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal shall not contain reference to cost; however resources information, such as data concerning labor hours and categories, materials, subcontracts, etc., shall be contained in the technical proposal so that your understanding of the Statement of Work (SOW) may be evaluated. It must disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

- d. Evaluation of Proposals: The Government will evaluate technical proposals in accordance with the criteria set forth in Section M, Evaluation/Award Criteria.
- e. Rejection of Proposals: The Government reserves the right to reject any or all proposals received. It is understood that your proposal will become part of the official contract file.
- f. Unnecessarily Elaborate Proposals: Unnecessarily elaborate brochures or other presentations beyond those sufficient to present a complete and effective proposal are not desired and may be construed as an indication of the offeror's lack of cost consciousness. Elaborate art work, expensive visual and other presentation aids are neither necessary nor wanted.
- g. Privacy Act: The Privacy Act of 1974 (Public Law (P.L.) 93-579) requires that a Federal agency advise each individual whom it asks to supply information: 1) the authority which authorized the solicitation; 2) whether disclosure is voluntary or mandatory; (3) the principal purpose or purposes for which the information is intended to be used; (4) the uses outside the agency which may be made of the information; and 4) the effects on the individual, if any, of not providing all or any part of the requested information.

Therefore:

- (1) The Government is requesting the information called for in this RFP pursuant to the authority provided by Section 301(g) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.
- (2) Provisions of the information requested are entirely voluntary.
- (3) The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.
- (4) Failure to provide any or all of the requested information may result in a less than adequate review.
- (5) The information provided by you may be routinely disclosed for the following purposes:
  - to the cognizant audit agency and the General Accounting Officer for auditing;
  - to the Department of Justice as required for litigation;
  - to respond to Congressional inquiries; and
  - to qualified experts, not within the definition of Department employees for opinions as a part of the review process.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of AHRQ contracting programs. Authority for requesting this information is provided by Section 305 and Title IV of the Public Health Service Act, as amended.

- h. The RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with this or any acquisition action.

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

## **L.9 TECHNICAL PROPOSAL INSTRUCTIONS**

The technical proposal shall contain an original and ten (10) copies. The technical proposal described below shall be limited to **150 pages** not including resumes or bibliographies, with no less than a 11 point pitch, with the majority of the text double-spaced (lists of deliverables, person loading charts, and similar materials need not be double-spaced, so long as they are legible).

- a. Recommended Technical Proposal Format

To assist in the expeditious and comprehensive evaluation of your proposal, the Government desires that you follow the guidelines and format listed below:

- (1) Cover Page: The name of the proposing organization, author(s) of the technical proposal, the RFP number and the title of the RFP should appear on the cover. One (1) manually signed original copy of the proposal and the number of copies specified in the RFP cover letter are required.
- (2) Table of Contents: Provide sufficient detail so that all important elements of the proposal can be located readily.
- (3) Introduction: This should be a one or two page summary outlining the proposed work, your interest in submitting a proposal, and the importance of this effort in relation to your overall operation.
- (4) Technical Discussion: The offeror shall prepare a technical discussion which addresses evaluation criteria 1, 2, 3, 4 and 5 below. Evaluation criteria 6 is to be prepared in accordance with Section L.10. The offeror shall further state that no

deviations or exceptions to the SOW are taken. The evaluation criteria are as follows:

1. Technical Approach
2. Management Plan
3. Organization/Corporate Experience
4. Qualifications of Proposed Staff, including Consultants
5. Facilities and Equipment
6. Past Performance (See Section L.10)

**Technical proposals submitted in response to this RFP shall address each of the items described below, and shall be organized in the same manner and within the page limitations specified. Proposals shall be prepared in double-spaced format, with numbered pages.**

## **1. Proposed Technical Approach**

The offeror shall submit a narrative which clearly addresses how he/she plans to develop, design, and implement the statement of work within the time constraints of the project. The proposal should include a narrative description of the approach to taken; an indication of the role of each organization involved in each task; a schedule showing the timing for the major tasks for the 2 years of the project period; and a discussion of the interrelationship of tasks. The narrative must demonstrate the contractor's understanding of the problems of patient safety, medical event reporting, classification and coding of events, their causes, voluntary and mandatory reporting requirements and issues of integration of healthcare databases. Discuss likely problems that may arise and your proposed approach to overcoming them. Indicate the rationale for your approach, citing comparable work you have done where this approach was successful.

Specifically, the offeror should describe the approach with respect to the requirements of this acquisition, including:

Approach to consensus development of coding and classification approaches;

Approach and methods for development and usability testing of web based input process;

Approach and methods for the development of user based software for local data storage and input;

Approach and methods to be used to develop a prototype data warehouse for integrating event reporting data and providing user feedback.

Approach to protecting data security and confidentiality;

The plan for development of Phase II and Phase III and development of the data warehouse.

## **2. Management Plan**

The offeror shall demonstrate their ability to achieve the delivery of performance requirements through the proposed use of corporate management and other personnel resources as well as demonstrate that the offeror's organizational structure and capabilities will meet the project's milestones in a timely manner.

The offeror shall provide:

- (1) An organization chart(s) which presents the placement of the project within the offeror's organization and the organization of the staff proposed for the project. The chart(s) shall show clear lines of authority and function.
- (2) A person-loading chart which presents the number of hours allocated to each task for each category of staff for each year of the contract and for the total contract. The chart should also delineate critical milestones and the deliverables for each.
- (3) Provide a fully supported narrative; showing offeror's understanding of the requirements in the Statement of Work from a managerial perspective. The narrative should at a minimum address the following topics:
  - labor skill mix determination (why you chose the skill mix for this project)
  - the percentage of full time core personnel (if a ratio of less than seventy percent full time core staff to thirty percent consultants/subcontractors is proposed, offeror shall provide a detailed explanation of how the proposed staffing plan ensures that the work is conducted by individuals with a mastery of the technical requirements of the Statement of Work).
  - monitoring and control of services provided: technical quality, responsiveness, cost control, and effective and efficient resource utilization, compliance with technical requirement and contract provisions. Clearly show proposed system for quality control of work performed including documents to be produced, and proposed system for management control and contract provision compliance;
  - managerial problems offeror expects to encounter. Describe the methods you propose to solve these problems. Demonstrate ability and flexibility to rapidly solve the same or similar managerial problems encountered previously;
  - ability and flexibility to respond rapidly to changes in budget, priorities, and schedule.
- (4) The offeror shall also describe proposed relationships with any subcontractors and/or consultants including how they intend to monitor their performance. In addition, the offeror shall provide letters of commitment between the offeror and any personnel other than current direct employees that includes dates of employment, specific tasks to be performed, and hours available each year for this project.

### **3. Organizational/Corporate Experience**



Offerors should list and summarize any contracts (state or federal) or grants (state, federal, or private foundation) recently completed (within the last 3 1/2 years - since January 1, 1999), or that are currently in process, and describe the relevance to the tasks, sub-tasks, and associated activities that may be performed under this contract. The Offeror shall demonstrate the extent, relevance, and quality of their corporate experience as it relates to the requirements of this acquisition, including the following:

At least 5 years of experience and demonstrated success in:

Developing web based user input systems for large healthcare data systems;

Developing formal systems for monitoring and maintaining efficiency and quality in the use of computer and programmer resources;

Development of training materials and support resources for computer database entry and analysis systems

Dealing with large complex health care data systems and databases;

Demonstrating the ability to maintain and manage multiple complex activities concurrently at the highest level of professional and scientific quality.

At least 3 years of experience in:

Patient safety and medical error related activities

#### **4. Qualifications of Proposed Staff, Including Consultants**

The offeror shall provide (1) the resumes of all key personnel (generally senior and junior technical staff) describing their qualifications as they relate to the requirements of this solicitation and (2) a person loading chart. The offeror is expected to be specific in describing the proposed personnel and their relevant qualifications and experience, including their background and experience as they relate to the requirements of this acquisition.

The offeror should also describe:

1) The experience of the Project Director as it relates to the requirements of this acquisition as evidenced by educational attainment, employment history, experience and specific professional, scientific or technical accomplishments, including the minimum experience requirements below. The Project Director should be a highly qualified senior staff member who is available on a day-to-day basis to direct and monitor the project contract and the associated technical tasks.

At least 5 years of experience in each of the following:

Directing the development and maintenance of a large data systems in direct support of health services research;

Data processing management, including responsibility for the recruitment and supervision of programming staff, directing multiple simultaneous data processing tasks, providing fiscal controls, and overseeing technical components in a timely and efficient manner;

Experience in health care coding and analysis systems;

The Project Director must also have experience exhibiting:

Excellent overall project management skills that include substantive/technical areas, teamwork, budget management, cost control, flexibility, and the ability to produce deliverables on-time, within budget, and of exceptionally high technical quality;

Excellent verbal and written communication skills.

2) The experience of staff and consultants as it relates to the requirements of this acquisition as evidenced by educational attainment, employment history, experience and specific professional, scientific or technical accomplishments.

Minimum requirements with respect to specific types of programming skill/experience are given below: Approximately one-half of the proposed staff should have each of the following:

5 years or more of experience regularly web based user input formats

2 years or more of formal education in a health-related field or social science;

3 years or more of experience in experience in using other large databases such as, but not limited to, data from the, CDC, CMS, FDA and/or AHRQ data systems

3 years experience in ICD coding and clinical software (DRGs, disease staging, etc.);

At least one programmer with 2 or more years experience in HTML programming and other web site support activities.

In addition, the contractor must provide:

At least 2 of the staff should be highly organized and detail oriented with excellent communication skills with 3 or more years of experience in coordinating with outside agencies, preparing agreements for the uses and restrictions of their data, overseeing the process of data purchase and collection, and providing technical assistance to data organizations.

At least one of the staff should have expertise with data confidentiality and security issues.

At least one of the staff should have expertise in the area of patient safety and medical error

## 5. Facilities and Equipment

The offeror shall describe the suitability, quality and cost-efficiency of their facilities and equipment available for the performance of all requirements of this acquisition. There will be daily interaction between agency research staff and the Offeror's staff so suitable logistical plans to facilitate communications and meetings must be addressed.

### L.10 Past Performance Information

Offerors shall submit the following information in an original and four (4) copies as part of their proposal for both the offeror and proposed major subcontractors:

- (1) Provide a listing of the offeror's recently completed (within the last 3 1/2 years - since January 1, 1999) and ongoing work (contracts and grants) directly related to the requirements of this acquisition. This listing shall include a brief description of each relevant project. Contracts or grants may include those entered into by the Federal Government, agencies of State and local governments and commercial customers. Offerors that are newly formed entities without prior contracts/grants should provide evaluations forms for contracts/grants and subcontracts as required above for all key personnel.

Include the following information for each contract, subcontract or grant:

- A. Name of contracting/grant activity
  - B. Contract/Grant number
  - C. Contract/Grant type
  - D. Total contract/grant value
  - E. Brief description of Contract/Grant
  - F. Contracting Officer and telephone number
  - G. Program Manager and telephone number
  - H. Administrative Contracting Officer, if different from F., and telephone number
  - I. List of major subcontractors
- (2) The offeror may provide information on problems encountered on the contracts, grants and subcontracts identified in (1) above and corrective actions taken to resolve those problems. Offerors should not provide general information on their performance on the identified contracts/grants. General performance information will be obtained from the evaluation forms.

- (3) The offeror may describe any quality awards or certifications that indicate the offeror possesses a high-quality process for developing and producing the product or service required. Identify what segment of the company (one division or the entire company) that received the award or certification. Describe when the award or certification was bestowed. If the award or certification is over three years old, present evidence that the qualifications still apply.
- (4) Each offeror will be evaluated on his/her performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations and as an evaluation factor against which offerors' relative rankings will be compared to assure best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the procurement under consideration.

The attached Past Performance Questionnaire and Contractor Performance Form shall be completed by those contracting organizations listed in (1) above. The evaluation forms shall be completed and forwarded directly to the following:

Darryl Grant  
Agency for Healthcare Research and Quality  
Contracts Management Staff  
2101 East Jefferson Street, Suite 502  
Rockville, Maryland 20852  
FAX: 301-443-7523

Evaluation forms must be received by **August 9, 2002** in order to be included in the review process. It is the responsibility of the offeror to ensure that these documents are forwarded to the Contracting Officer.

## **L.11 BUSINESS PROPOSAL**

The offeror shall submit as part of the proposal a separate enclosure titled "Business Proposal." The Business Proposal shall include the Cost/Price Proposal and Other Administrative Data in accordance with the following:

### **A. Cost/Price Proposal**

1. The cost/price proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. The proposal costs should be provided by task, per project year, for each of the 2 years in addition to a cumulative cost by task.

A cost proposal, in the amount of an original and four (4) copies, shall be provided. As appropriate, cost breakdowns shall be provided for the following cost elements:

- (a) Direct Labor

The estimated cost for all personnel who will be assigned for direct work on this project shall be included. Give the name, title, percent of effort or time, salary and fringe benefits, for each employee.

Salary increases that are anticipated during performance of a resultant contract should be proposed as a cost. If escalation is included, state the degree (percent) and methodology, e.g., annual flat rate applied to a base rate as of a specific date or a mid-pointed rate for the period of performance. State whether any additional direct labor (new hires) will be required during the performance period of this procurement. If so, state the number required and anticipated date of hire. Also, specify the month and day on which your fiscal year commences.

(b) Supplies and Equipment

Include description, unit price, quantity, total price, justification for purchasing or leasing items and the basis for pricing (vendor quotes, invoice prices, etc.).

(c) Travel

The amount proposed for travel shall be supported with a breakdown which includes purpose, destination, duration, and estimated cost (transportation and per diem) for each proposed trip. If travel costs are proposed on the basis of your organization's established travel policy, a copy of the policy must be provided.

(d) Consultants

This element should include names(s) of consultant, number of days, and daily rate. The method of obtaining each consultant, either sole source or competitive, and the degree of competition or the rationale for sole source shall be explained.

(e) Subcontractors

Subcontractor costs shall be broken down in sufficient detail adequate to establish the reasonableness of the proposed amount. Support documentation should include degree of subcontract competition and basis for selecting source.

(f) Other Direct Costs

Any proposed other direct costs shall be supported with breakdown outlining the separate costs proposed and details supporting the formulation of the costs proposed. A signed agreement between the offeror and any personnel other than direct employees that includes dates of employment, salary, and specific tasks to be performed should be included.

(g) Indirect Costs

Indicate how you have computed and applied indirect costs, and provide a basis for evaluating the reasonableness of the proposed rates. Where a rate agreement exists, provide a copy.

2. Certified documentation indicating that the offeror has a cost accounting system in place which allows for the collection, tracking and reporting of all costs under a cost reimbursement-type contract.
3. Certified documentation that the offeror has a current indirect cost rate agreement in place with a federal agency or that is in the process of obtaining or revising such an agreement. A copy of the indirect cost rate agreement or the proposed rate agreement shall be provided.

B. Other Administrative Data

- (1) Terms and Conditions: The proposal shall stipulate that it is predicated upon the terms and conditions of the RFP. In addition, it shall contain a statement to the effect that it is firm for a period of at least 120 days from the date of receipt thereof by the Government.

Minimum Bid Acceptance Period (April 1984)

- (a) "Acceptance period," as used in this provision, means the number of calendar days available to the Government for awarding a contract from the date specified in this solicitation for receipt of bids.
  - (b) This provision supersedes any language pertaining to the acceptance period that may appear elsewhere in this solicitation.
  - (c) The Government requires a minimum acceptance period of 120 days.
  - (d) A bid allowing less than the Government's minimum acceptance period may be rejected.
  - (e) The bidder agrees to execute all that it has undertaken to do, in compliance with its bid, if that bid is accepted in writing within (i) the acceptance period stated in paragraph (3) above, or (ii) any longer acceptance period stated in paragraph (4) above.
- (2) Authority to Conduct Negotiations: The proposal shall list the names and telephone numbers of persons authorized to conduct negotiations and to execute contracts.

- (3) Property:
- (a) It is HHS policy that contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the contracting officer. If additional equipment must be acquired, you shall include the description, estimated cost of each item and whether you will furnish such items with your own funds.
  - (b) You shall identify Government-owned property in your possession and/or property acquired from Federal funds to which you have title, that is proposed to be used in the performance of the prospective contract.
  - (c) The management and control of any Government property shall be in accordance with HHS Publication (OS) 74-115 entitled, Contractor's Guide for Control of Government Property" 1990, a copy of which will be provided upon request.
- (4) Royalties: You shall furnish information concerning royalties which are anticipated to be paid in connection with the performance of work under the proposed contract.
- (5) Commitments: You shall list other commitments with the Government relating to the specified work or services and indicate whether these commitments will or will not interfere with the completion of work and/or services contemplated under this proposal.
- (6) Financial Capacity: You shall provide sufficient data to indicate that you have the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source. (Financial data such as balance sheets, profit and loss statements, cash forecasts, and financial histories of your organization's affiliated concerns should be utilized.)
- (7) Performance Capability: You shall provide acceptable evidence of your "ability to obtain" equipment, facilities, and personnel necessary to perform the requirements of this project. If these are not represented in your current operations, they should normally be supported by commitment or explicit arrangement, which is in existence at the time the contract is to be awarded, for the rental, purchase, or other acquisition of such resources, equipment, facilities, or personnel. In addition, you shall indicate your ability to comply with the required or proposed delivery or performance schedule taking into consideration all existing business commitments, commercial as well as Government.
- (8) Representations and Certifications: Section K, "Representations and Certifications and Other Statements of Offerors" shall be completed and signed

by an official authorized to bind your organization. **This section shall be made a part of the original business proposal**

## **L.12 SELECTION OF OFFERORS**

- a. The acceptability of the technical portion of each contract proposal will be evaluated by the technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a limited cost review, management analysis, etc.
- c. The Contracting Officer will, in concert with Agency staff, evaluate past performance of the technically acceptable offerors and decide which proposals are in the competitive range. Oral or written discussions will be conducted with all offerors in the competitive range, if necessary. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. Final Proposal Revisions will be requested with the reservation of the right to conduct limited negotiations after submission of the Final Proposal Revisions.
- d. A final best-buy analysis will be performed taking into consideration the results of the technical evaluation, cost analysis, past performance, and ability to complete the work within the Government's required schedule. The Government reserves the right to make an award to the best advantage of the Government, technical merit, cost, past performance, and other factors considered.
- e. The Government reserves the right to make a single award, multiple awards, or no award at all to the RFP.



## **SECTION M - EVALUATION FACTORS FOR AWARD**

1. Selection of an offeror for contract award will be based on an evaluation of proposals against three factors and award will be made to that responsible offeror whose proposal is most advantageous to the Government. The three factors are: technical, cost, and past performance. The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. Offerors that submit technically acceptable proposals will then be evaluated for past performance. Following the evaluation of the offeror's past performance, a competitive range will be determined.
2. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection in the event that two or more offerors are determined to be essentially equal following the evaluation of all factors other than cost or price. In any event, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government. The Government reserves the right to make a single award, multiple awards, or no award at all.

### **THE GOVERNMENT RESERVES THE RIGHT TO MAKE AN AWARD WITHOUT DISCUSSION**

3. All proposals will be reviewed in accordance with the governing regulations and AHRQ policies and procedures. The technical proposal and past performance information will be evaluated in terms of the offeror's responses to each of the evaluation factors. Each proposal will be evaluated on the likelihood of meeting the Government's requirements. The evaluation factors and assigned weights which will be used in the overall review of the offeror's proposal are outlined below. The technical proposal shall consist of the responses to evaluation criteria 1 through 5. The offeror should show that the objectives stated in the proposal are understood and offer a logical program for their achievement. The following criteria will be used to evaluate proposals and will be weighted as indicated in establishing a numerical rating for all proposals submitted. Factors facilitating the evaluation of each criteria below are referenced in the corresponding criteria found in Section L of this solicitation:

***OFFERORS PLEASE NOTE:*** Evaluation Criteria 1 through 5, for a total of 100 points, will be evaluated by a peer review technical committee, who will also recommend technical acceptability or unacceptability of the proposal. Agency staff and contracting personnel will review and evaluate Criteria 6 for a total of 10 points. The total possible points for Evaluation Criteria 1 through 6 is 110 points.

## **EVALUATION CRITERIA**

## **WEIGHT**

### **1. Technical Approach**

**(35 points)**

The offeror's technical approach will be evaluated on how clearly and concisely the proposal presents a detailed plan to accomplish all requirements in the statement of work within the time constraints of the project. Specifically, the proposal shall be evaluated on the reasonableness, clarity and feasibility of the timeline and technical approach, including the contractors:

- understanding of the problems of patient safety, medical event reporting, classification and coding of events, their causes, voluntary and mandatory reporting requirements and issues of integration of healthcare databases.
- design and development of web-based user data input approaches and methods
- approaches to methods for consensus development of coding and classification processes;
- design and development of prototype data warehouse
- development of training materials to support utilization
- the soundness of proposed prototype testing approaches; and

### **2. Management Plan**

**(20 points)**

The management plan will be evaluated on the appropriateness of the organizational structure and management systems, their management of subcontractors/consultants, their ability to handle multiple simultaneous tasks with competing needs, their ability to work with multiple agencies, the person-days proposed, the plan for ensuring availability of adequate staff, the planned methods for assuring the successful completion of all tasks within the time and budget allocated, the reasonableness of the selection criteria to be used in forming the external advisory panel and the manner in which the offeror will work with the various agencies of the PSTF.

### **3. Organizational/Corporate Experience**

**(20 points)**

Proposals will be evaluated as to the extent, relevance and quality of the offerors organizational/corporate experience as it relates to the requirements of this acquisition.

### **4. Personnel**

**(20 points)**

The resumes of proposed key personnel and consultants will be evaluated for documented experience, educational background and training as they relate to the requirements of this acquisition. The availability of proposed staff and their designated responsibility on the project will be evaluated.

**5. Facilities and Equipment ( 5 points)**

Offerors will be evaluated on the adequacy of the resources available to compete the requirements of this acquisition including the adequacy of computer hardware and software, the availability of a staff trained in web development and database integration.

**6. Past Performance (10 points)**

Offerors will be evaluated on their past performance(since January 1, 1999).

The offerors' past performance will be evaluated on the basis of the following factors:

- (a) **Quality:** How well the contractor conformed to the performance standard in providing the research services or achieved the stated objective of the contract or grant. Quality will be evaluated by the personnel provided, the level of effort agreed to in the contract statement of work or grant, and quality of final products (e.g., written reports).
- (b) **Timeliness:** How well the contractor adheres to time-tables and delivery schedules in providing the research services or products. Consideration is given to contractor's effort to recommend and/or take corrective actions to keep the contract or grant on schedule.
- (c) **Customer-satisfaction:** Rates the professional and cooperative behavior of the contractor or grantee with the client.
- (d) **Cost control:** Rates the cost-effectiveness of the contractor or grantee in conducting the research.

Assessment of the offeror's past performance will be one means of evaluating the credibility of the offeror's proposal, and relative capability to meet performance requirements.

- j. The completed questionnaires will provide a basis for determining past performance evaluation as well as information obtained from the references listed in the proposal, other customers known to the Government, consumer protection organizations, and others who may have useful and relevant information. Information will also be considered regarding any significant subcontractors and key personnel records. Past performance will be scored on a range from 0 to 10, with 10 being the most favorable.

Evaluation of past performance will often be quite subjective based on consideration of all relevant facts and circumstances. It will not be based on absolute standards of acceptable performance. The Government is seeking to determine whether the offeror has consistently demonstrated a commitment to customer satisfaction and timely delivery of services at fair and reasonable prices.

The assessment of the offeror's past performance will be used as a means of evaluating the relative capability of the offeror and the other competitors. Thus, an offeror with an exceptional record of past performance may receive a more favorable evaluation than

another whose record is acceptable, even though both may have acceptable technical proposals.

By past performance, the Government means the offeror's record of conforming to specifications and to standards of good workmanship; the contractor's record of forecasting and controlling costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the number or severity of an offeror's problems, the effectiveness of corrective actions taken, the offeror's overall work record, and the age and relevance of past performance information.

The lack of a performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

The Government reserves the right to evaluate relevant past performance information not specifically provided by the offeror.

## Attachment 1

### Reference Materials

This section identifies materials mentioned in the scope of work, as well as other materials that may be useful to potential offerors.

Barach P., Small SD Reporting and Preventing Medical Mishaps: Lessons from Non-medical Near Miss Reporting Systems. *BMJ* 2000; 320:759-763. (see **Attachment 5**)

Battles JB, Kaplan HS, van der Schaaf TW, Shea CE. The attributes of medical event reporting systems. *Archives of Pathology Laboratory Medicine*; 1998; 122:3:132-138. (see **Attachment 6**)

Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. *Acad Med* 2001;76:2:125-133. (see **Attachment 7**)

Battles JB and Sheridan, M. A model for resource materials to support in-service and faculty development program activities. *Journal of Biocommunication*. 1989;16:3:9-13.

Kaplan HS, Battles JB, van der Schaaf TW, Shea CE, Mercer SQ. Identification and classification of the causes of events in transfusion medicine. *Transfusion*. 1998 38: 1071-1081. (see **Attachment 8**)

Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human; Building a Safer Health System*. Washington, D.C.: National Academy Press, 1999.

Quality Interagency Task Force. *Report to the President: Doing what counts for patient safety-Federal actions to reduce medical errors and their impact*. February, 2000.

Rasmussen J. The definition of human error and a taxonomy for technical systems design. In: Rasmussen J, Duncan K, Leplat, J. eds. *New technology and human error*. London: Wiley, 1987. 23-30.

Rasmussen J. *Information processing and human-machine interaction: an approach to cognitive engineering*. New York: Elsevier, 1986.

Reason J. *Human Error*. Cambridge: Cambridge University, 1990.

Reason J. *Managing the organizational accident*. New York: Ashgate, 1997.

## **Attachment 2**

Federal Government web sites are subject to a variety of regulations and guidance, the applicability of which depends somewhat on the nature of the content of the web sites. However, all Federal web sites are subject to accessibility and privacy act guidance. The following resources should serve as a guide to answering contractor questions.

### **Accessibility Requirements:**

<http://www.hhs.gov/siteinfo/508synopsis.html>

### **Privacy Guidance on Federal Web Pages**

<http://www.whitehouse.gov/omb/memoranda/m99-05-b.html>  
and  
<http://www.whitehouse.gov/omb/memoranda/m99-18.html>

### **Children's Privacy Guidance:**

<http://www.hhs.gov/kids/parentnote.html>

### **General Web Page Guidance**

<http://www.hhs.gov/policy/internet/webcust.html>

### **Information Collection Guidance:**

<http://www.hhs.gov/oirm/infocollect/irm402a.html>

### **Rules on Sharing Data among Agencies:**

<http://www.whitehouse.gov/omb/memoranda/m01-05.html>

### **Domain Name Policy:**

<http://www.hhs.gov/read/irmpolicy/0008.html#1>

### **Use of Persistent Cookies:**

<http://www.hhs.gov/read/irmpolicy/0009.html>

### **Links to External Web Sites (example language)**

<http://www.aoa.gov/links.html>

Attachment 9

PAST PERFORMANCE QUESTIONNAIRE

PART ONE: INSTRUCTIONS

The offeror listed below has submitted a proposal in response to the Agency for Healthcare Research and Quality (AHRQ) Solicitation No. AHRQ-02-0015, entitled "Patient Safety Database." Past performance is an important part of the evaluation criteria for this acquisition, so input from previous customers of the offeror is important. This office would greatly appreciate you taking the time to complete this form. **This information is to be provided to Mr. Darryl Grant, the AHRQ Contracting Officer and is NOT to be disclosed to the offeror either verbally or in writing.** Please provide an honest assessment and return to AHRQ to the address shown below, no later than **August 9, 2002**. If you have any questions, please contact Mr. Darryl Grant at (301) 594-7189.

Mr. Darryl Grant  
Agency for Healthcare Research and Quality  
Division of Contracts Management  
2101 East Jefferson Street, Suite 502  
Rockville, Maryland 20852

FAX: (301) 443-7523

NAME OF OFFEROR: \_\_\_\_\_

ADDRESS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Contractor Performance Form**

1. Name of Contractor: \_\_\_\_\_
2. Address: \_\_\_\_\_  
\_\_\_\_\_
3. Contract/Grant Number: \_\_\_\_\_
4. Contract/Grant Value (Base Plus Options): \_\_\_\_\_
5. Contract/Grant Award Date: \_\_\_\_\_
6. Contract/Grant Completion Date: \_\_\_\_\_
7. Type of Contract/Grant: (Check all that apply)  FP  FPI  FP-EPA  
 Award Fee  CPFF-Completion  CPFF-Term  CPIF  CPAF  
 IO/IQ  BOA  Requirements  Labor-Hour  T&M  SBSA  
 8(a)  SBIR  Sealed Bid  Negotiated  Competitive  Non-Competitive
8. Description of Requirement:



**CONTRACTOR’S PERFORMANCE RATING**

Ratings: Summarize contractor performance and circle in the column on the right the number which corresponds to the performance rating for each rating category. Please see reverse page for explanation of rating scale.

Quality of Product or Service	Comments	0 1 2 3 4 5
Cost Control	Comments	0 1 2 3 4 5
Timeliness of Performance	Comments	0 1 2 3 4 5
Business Relations	Comments	0 1 2 3 4 5

Customer Satisfaction - Is/was the Contractor committed to customer satisfaction?   Yes   No ; Would you use this Contractor again?   Yes   No

Reason:

**NAME OF EVALUATOR:** \_\_\_\_\_

**TITLE OF EVALUATOR:** \_\_\_\_\_

**SIGNATURE OF EVALUATOR:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

**MAILING ADDRESS:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**PHONE #:** \_\_\_\_\_

**Rating Guidelines:** Summarize contractor performance in each of the rating areas. Assign each area a rating 0(Unsatisfactory), 1(Poor), 2(Fair), 3(Good), 4(Excellent) 5(Outstanding). Use the following instructions as guidance in making these evaluations.

	<b>Quality</b>	<b>Cost Control</b>	<b>Timeliness of Performance</b>	<b>Business Relation</b>
	-Compliance with contract requirements -Accuracy of reports -Technical excellence	-Within budget(over/under target costs) -Current, accurate, and complete billings -Relationship of negotiated costs to actual -Cost efficiencies -Change orders issue	-Met interim milestones -Reliable -Responsive to technical direction -Completed on time, including wrap-up and contract adm -No liquidated damages assessed	-Effective management -Businesslike correspondence -Responsive to contract requirements -Prompt notification of problems -Reasonable/cooperative -Flexible -Pro-active -Effective small/small disadvantaged business sub-contracting program
0-unsatisfactory	Nonconformances are jeopardizing the achievement of contract requirements, despite use of Agency resources	Ability to manage cost issues is jeopardizing performance of contract requirements, despite use of Agency resources	Delays are jeopardizing the achievement of contract requirements, despite use of Agency's resources	Response to inquiries, technical/service/administrative issues is not effective
1-Poor	Overall compliance requires major Agency resources to ensure achievement of contract requirements	Ability to manage cost issues requires major Agency resources to ensure achievement of contract requirements	Delays require major Agency resources to ensure achievement of contract requirements	Response to inquiries, technical/service/administrative issues is marginally effective
2-Fair	Overall compliance requires minor Agency resources to ensure achievement of contract requirements	Ability to manage cost issues requires minor Agency resources to ensure achievement of contract requirements	Delays require minor Agency resources to ensure achievement of contract requirements	Response to inquiries, technical/service/administrative issues is somewhat effective
3-Good	Overall compliance does not impact achievement of contract requirements	Management of cost issues does not impact achievement of contract requirements	Delays do not impact achievement of contract requirements	Response to inquiries, technical/service/administrative issues is usually effective
4-Excellent	There are no quality problems	There are no cost management issues	There are no delays	Response to inquiries, technical/service/administrative issues is effective

5-Outstanding. The Contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where Contractor performance clearly exceeds the performance levels described as "Excellent."



**DISCLOSURE OF LOBBYING ACTIVITIES  
CONTINUATION SHEET**

Approved by OMB  
0348-0046

Reporting Entity: \_\_\_\_\_ Page \_\_\_\_\_ of \_\_\_\_\_

Authorized for Local Reproduction  
Standard Form--LLL-A

## INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee of prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subawardee recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.  
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.