Amendment #1 (Questions and Answers) to RFP-NIH-NIAID-DMID-03-34

"Biodefense and Emerging Infections Research Resources Program"

Amendment to Solicitation No.:	NIH-NIAID-DMID-03-34
Amendment No.:	1 (1st posting)
Amendment Date:	February 5, 2003
RFP Issue Date:	December 9, 2002
Issued By:	Jacqueline C. Holden Senior Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Janet M. Mattson, Contract Specialist
Name and Address of Offeror:	To All Offerors

The above referenced solicitation is hereby amended as follows to respond to questions presented by recipients of this RFP. The responses are offered for information only and do not modify or become part of this solicitation. This Amendment will be updated to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment #1 for additional Q&A.

Question 1. Can the Principal Investigator (PI) also be the Responsible Official (RO) for Select Agents if the PI will not be directly handling or transferring the agents?

According to the Centers for Disease Control (CDC) Select Agent Program, the PI of the Biodefense Resource Program (BRP) contract under this RFP cannot serve as the Responsible Official (RO) for the entity or institution. The RO represents the institution on all issues concerning shipping and receipt of Select Agents. See http://www.cdc.gov/od/ohs/lrsat.htm and http://www.cdc.gov/od/sap/docs/42cfr73.pdf for additional information concerning guidelines and regulation for the CDC Select Agent Program.

Question 2. Some reagents may be difficult to procure without negotiating a material transfer agreement (MTA) or licensing agreement with the provider to protect their intellectual property rights.

a) Will the acquisition process proposed for this project allow the contractor to accept MTAs from donor institutions that might restrict the use of the reagents to non-commercial purposes?

Yes, the proposed acquisition process will permit the contractor to accept agents or materials from donor institutions under MTAs that may restrict their use to non-commercial research activities only.

(b) Is funding being provided to pay licensing and royalty fees to depositors for material accepted into the BRP?

This is currently being researched by the NIH Office of Technology Transfer.

Question 3. Can a list of the items represented by the 5000 samples to be transferred from the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) be provided to offerors?

The exact inventory of samples to be transferred from USAMRIID to the BRP will be determined at a later date. The samples will be predominantly NIAID Category A, B and C Priority Pathogens and emerging infectious disease organisms as stated in the RFP and will include some reagents for basic research. The materials will not include any agents or materials that require access to or storage in BSL-4 facilities.

Question 4. Does everyone involved in the activity need to be bonded, or only those who deliver the material or handle money?

Due to recent changes in the Interim Final Rule for Possession, Use and Transfer of Select Agents and Toxins (Select Agent Rules) http://www.cdc.gov/od/sap/docs/42cfr73.pdf, contractor employees who will be involved in the BRP repository activities with Select Agents may require a Department of Justice (DOJ) Security Risk Assessment as detailed under Part 73.8 of the Federal Register publication. Applicants are advised to keep appraised of additional changes to this Interim Final Rule through the CDC web site at http://www.cdc.gov/od/ohs/lrsat.htm and http://www.cdc.gov/od/sap/. The CDC and DOJ have not determined how these risk assessments will be carried out.

Question 5. There is a history of companies incurring significant legal expense associated with the shipment of these types of materials. Will the Federal Government indemnify the contractor?

Indemnification is not determined until after award.

Question 6. In Section L.1.e (Estimate of Effort) the government is estimating 196,000 labor hours/seven years. Does the 196,000 hours cover the seven-year period (this equates to approximately 14 FTEs) or is the 196,000 hours an annual estimate?

The 196,000 hr is the estimate for the total estimated labor hours for lifetime of the contract for a period of 7 years, or approximately 14 FTE annually.

Question 7. Can you provide an estimate of the number of outgoing shipments from the BRP to recipients?

It is estimated that there will be approximately 1,500 outgoing shipments during the first year of the contract.

Question 8. Page 25 of the RFP states "the technical proposal is limited to not-to exceed 100 pages, including appendices, attachments, operating manuals, non-scannable figures or data, letters of intent, etc ... ". We ask NIAID to reconsider this page limitation and exclude appendices, attachments, operating manuals, non-scannable figures or data, letters of intent, etc ... from the page limit.

The technical proposal is limited to 100 pages. The appendices, attachments, operating manuals, letters of intent must be submitted in the same technical proposal pdf file. These additional materials will not count against the 100 page limitation.

Question 9. Given the requirements on page 51 of the RFP to provide: (5) "Resumes and explanations of previous efforts provided for the Principal Investigator, Registration/Tracking Manager, Senior Scientists, Registration/Tracking Assistants, Shipping Manager, Administrative Assistant, Security Officer, Materials Handler, and Inventory Assistant", and (6) "proposed standard operating procedures. . .and samples of inventory control procedures and chain of custody", we request that the resumes, standard operating procedures, samples of inventory control procedures, and chain of custody also be excluded from the 100-page limitation.

Resumes and explanations of duties for the contractor staff will not count against the 100-page limitation for the technical proposal. However, these resumes are limited to 3 pages for the PI and Senior Scientists and 2 pages for all other personnel. These must be submitted as part of the same pdf file that contains the technical proposal.

Standard operating procedures (SOP), inventory control and chain of custody are also excluded from the 100 page limit. These documents must be submitted as part of the same pdf file that contains the technical proposal. An abbreviated version of the SOP or a summary of the SOP can be submitted in lieu of the complete document.

Question 10. Would the development of a custom Bacillus anthracis microarray qualify for this program (RFP)? It wasn't clear to me whether the definition of 'reagent' as stated in the proposal guidelines would include this sort of project. The microarrays would be used primarily for gene expression studies designed to identify new vaccine/antimicrobial targets, and could also be used for identification and diagnostics.

No, the development and production of microarrays does not qualify under this RFP. Under another existing NIAID contract, the Division of Microbiology and Infectious Diseases will continue to develop and produce microarrays for research purposes for biodefense select agents and emerging pathogens.

Question 11. Page 8, Item 5 Ship and Receive Reagents, a. Can the Government estimate the percentage of international versus domestic shipments a year? Also, can an estimate be provided of the anticipated growth in shipments over the seven years of the contract?

It is estimated that more 95% of the shipments will be domestic, less than 5% will be foreign.

Question 12. Page 8, Item 5 Ship and Receive Reagents, d. The RFP states the contractor shall delineate specific safety standards for the safe handling and use of specific reagents, in compliance with State and Federal regulations. Can the Government clarify this work requirement?

The offeror would be hesitant to try to provide specific safety standards for the laboratories using these reagents as this would incur a liability on the part of the contractor. In addition, it would require consulting with various experts on the different organisms, viruses, etc. and thus serve as a third party in passing this information along to the users.

The offeror must follow all CDC, USDA, other Federal and State guidelines and regulations, including the newly revised Appendix F of the Biosafety in Microbiological and Biomedical Laboratories, for the secure and safe handling of Select Agents, emerging pathogens and other biological materials in the contractor's own facility. The contractor is not expected to provide such guidelines to the recipients for materials distributed from the repository. Each recipient laboratory or facility is responsible for implementing and adhering to Federal and State safety and security guidelines in their own facilities.

Question 13. Page 8, Item 5 Ship and Receive Reagents, f. Can the Government estimate the number of imports per year of reagents and drugs?

It is expected that the number of reagents imported from foreign countries will be less than 15% of the total of all reagents obtained for the BRP.

Question 14. Page 9, Item 6 Disseminate Public Information, d. Can the Government estimate the breakdown of US versus international mailings of catalogs?

It is estimated that more than 90% of such mailings will be domestic, and less than 10% foreign.

Question 15. Page 9, Item 6 Disseminate Public Information, e. Can the Government estimate the number of journals per year in which descriptions of the BRP will be published, and which year this will start?

It is expected that this will initially occur during the 2nd or 3^{r} year of the contract and will include descriptions in 4-6 major scientific journals. The exact details will be determined at a later date.

Question 16. Page 9, Item 8 Provide Support for BRP-Sponsored Workshops. Can the Government estimate the number of workshops per year, and which year these will start?

See Section L, 2. Instructions to Offerors, c. Additional Cost and Technical Proposal Instructions, (2) Uniform Assumption – Cost (page 50). "For the purposes of preparing a budget, assume two, one-day workshops annually, 10 out-of-town invitees (non-federal) to be held in the Washington D.C. area." The exact details will

be determined at a later date.

Question 17. Page 14, Reporting Requirements. Can any of the information required in the monthly reports (for example, all of the information required in 2 such as the inventory, list of assayed reagents, etc.) be provided electronically? If so, what format (CD, disk, or email)?

Yes, the inventory lists, reagents assayed etc will be acceptable in electronic format on a CD disc.

Question 18. Page 50, c. (2) The RFP states the BRP will need 50 cubic feet of 'low temperature space' initially and this will grow to 200 cubic feet at the end of the contract. Can the Government clarify what percentage of the cubic feet storage required will be needed for -80C and liquid nitrogen?

It is expected that 50% of the required storage space will be liquid nitrogen, and 50% will be at –80C.

Question 19. Section M.4 under Criteria A.Technical Approach indicates the section is weighted at 55 points. The sub-categories under the heading total 65 points. Please clarify.

The 10 points listed on page 61 under (A) Technical Approach (2) BRP Contract Management (b) Inventory Control and Distribution was included in error and should be deleted.

The 55 points assigned for A. Technical Approach consists of: 30 points for (1) Initial Reagent Management, Production and Quality Control and 25 points for (2) BRP Contract Management. The 25 points assigned for B. Personnel Qualifications consists of: 15 points for (1) Training and Experience – Principal Investigator and 10 points for (2) Training and Experience – Support. C. Facilities and Resources is assigned 20 points. The total is 100 points.

Question 20. Is this RFP open to bids by Federal entities or national laboratories?

Yes.

Question 21. Is there a geographic or regional preference in locating the BRP?

There is no geographic or regional preference for the location of the BRP.

Question 22. Will existing repositories be consolidated in this program and if so what repositories, where are they currently located, and who is managing these programs?

No other NIAID repositories are planned for consolidation into this repository.

Question 23. The assumptions for reagent acquisition and expansion outlined on page 50 paragraph 3 are based on experience with what other reagent programs?

The assumptions in this RFP are based on the experience with the NIAID/NIH AIDS Research and Reference Reagent Program and other NIAID programs.

Question 24. Must the contractor have access to GMP production facilities or will they only be asked to store GMP materials?

It is anticipated that at some time in the life of this contract that access to GMP production facilities may be necessary. Access to GMP could be through a subcontractor. At the current time it is not possible to forecast the type of material(s) that would require GMP production. Additionally, the contractor may be asked to store materials produced by others under GMP for later distribution.

Question 25. The 196,000 hours of labor/seven years (page 33, Estimate of Effort) or 28,000 hours per year total effort seems low based on a budget assumption of $10,000,000 per year (page 50, paragraph 2) for only tasks 1 and

2 of the SOW. Are these numbers stated correctly? Are we correct in understanding that the budgets for tasks 3-11 of the SOW would be additional to that outlined for tasks 1 and 2?

The estimated $10,000,000 per year is for acquisition, expansion, production and storage of reagents and materials under Tasks 1 and 2. This can be accomplished either by the prime contractor or through subcontracts with the Government's approval. The Government estimated labor hours provided in the RFP are for information purposes only and apply to all 11 Tasks outlined in the SOW. The estimates provided in the RFP are not restrictive for purposes of proposal preparation.

Question 26. The new interim final Select Agent Rules issued by the CDC provides a timeline that states the date by which those institutions and entities must be registered, February 7, 2003. If an offeror for this RFP is not registered with the CDC, can they still apply for this RFP?

This entire RFP and subsequent contract concerns the receipt, possession and shipping of Select Agents and offerors applying under this RFP should be registered with CDC or the USDA as an organization or entity possessing Select Agents by February 7, 2003 in order to be grand fathered in under the proposed timeline, http://www.cdc.gov/od/sap/docs/timeline.pdf. Any entity not registered with CDC or USDA on February 7 must become fully compliant with all the proposed rules immediately upon registering after February 7 if they are to possess any Select Agents. The exact interpretation and implementation of some these proposed rules has not finalized. The CDC and Department of Justice are expected to issue guidance for these proposed rules over the next 9 months for previously registered entities (prior to February 7) to remain complaint with the regulations and laws. An offeror who either is or is not registered on February 7, 2003 must at the time of submission of Final Proposal Revisions (FPR) provide evidence of current up-to-date registration and compliance with CDC or USDA Select Agent rules and regulations to be selected for this contract.

- Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.
- The hour and date specified for receipt of offers REMAINS: **March 20, 2003, 4:00 PM, EST**.
- Offerors must acknowledge receipt of this Amendment #1, on each copy of the proposal submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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