AMENDMENT OF NIAID SOLICITATION

"Medical Countermeasures Against Radiological Threats: Product Development Support Services"

Solicitation Number:	RFP NIH-NIAID-DAIT-05-37
Amendment Number:	Two (2)
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Proposal Intent Response Sheet Due Date:	Friday, May 27, 2005 **(UNCHANGED)**
Proposal Due Date:	Friday, June 10, 2005 at 4:00 PM Local Time **(UNCHANGED)**
Issued By:	Carl A. Newman Contracting Officer NIAID, NIH, DHHS Contract Management Program, DEA 6700-B Rockledge Drive Room 3214 **(CHANGED)**, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	E-Mail: cn109s@nih.gov

This amendment is issued to all potential Offerors.

The above numbered solicitation is amended as set forth below. The date specified for receipt of proposals **HAS NOT** been changed. Offerors must acknowledge receipt of this and all other amendments, by identifying this amendment number (and any others) on each copy of any offer(s) submitted. Failure to receive your acknowledgement may result in the rejection of your offer. If, by virtue of this amendment, you wish to change an offer already submitted, such changes may be made by telegram, letter or e-mail, provided each telegram, letter or e-mail makes reference to this solicitation amendment number and is received prior to the opening hour and date specified. Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

PURPOSE OF AMENDMENT: This amendment answers the following six questions:

Question 1: Page 34 Appendix A of the RFP states: “It is strongly recommended that offerors use the following template as the table of contents for the technical proposal.” However, it does not appear that the template was provided.

Answer: The template was not provided. Please prepare the table of contents for the technical proposal without the template.

Question 2: The technical proposal is to include a Targeted/Planned Enrollment Table. It is likely that multiple clinical trials will be conducted under this contract with vastly different designs and number of subjects. Could the government provide some guidance on assumptions for the type of clinical trial for which they would like to see a Targeted/Planned Enrollment Table?

Answer: The government does not know the actual number or specific type of clinical studies that will be required over the performance period. However, since NIAID is going to be licensing countermeasures using the Animal Rule, Phase I safety and pharmacokinetic studies will be required. For each work assignment requiring a specific clinical study, the Contractor shall submit a proposal which will account for the Targeted Planned Enrollment table information.

Question 3: Could the government provide an example of the types of devices/*in vitro* diagnostic tests that would be licensed under a 510(k) or PMA as result of the research performed under this contract?

Answer: At this time, the government does not know the specific methods, technology or devices that will be developed as diagnostic or biodosimetry devices. It is hopeful that a diagnostic or biodosimetry device or concept currently in research and development will provide the capability to measure an individual's level of exposure to radiation. We are looking for experience and capabilities to support such a product licensure.

Question 4: Would the government consider lifting the technical proposal page restrictions?

Answer: In accordance with the RFP, Block 8 (Technical Proposal Page Limits), the page limitations shall be 150 pages as noted.

Question 5: For the cost proposal, uniform budget assumptions are given for each contract year on page 41 of the RFP. However, the assumptions in the table do not address many of the tasks in the scope of work. For example, preparation of INDs, conduct of clinical trials, overall project management, establishment of project specific information systems, etc. Given the nature of the work assignment requests, are the uniform pricing assumptions intended to exclude costs for these other program areas for bidding purposes given the uncertainty of the product's development plan or does the government want a comprehensive cost proposal and, if so, can uniform pricing assumptions be provided for other contract deliverables listed on pages 17 and 18 of the RFP (e.g., number of Phase 1 clinical trials per year – assume that all trial activities are concluded in a one-year time frame including analysis and final report; number of INDs to be prepared and submitted to the FDA per year).

Answer: As noted in the RFP, Appendix A, Paragraph a, item 2, each work assignment shall be written for the conduct of a specific, finite task. Each work assignment will outline the tasks and list the deliverables to be priced.

Question 6: Page 41, Year 1 asks for budgets for "Arrange and manage Pre-IND meeting with FDA: One meeting and one package; and, Prepare and submit documents for NDA/BLA submission: One licensed product (new label indication)."

Years 2-5 instructs us to "Assume twice the effort of year one for subsequent years". We have made this assumption for our Phase I clinical study budgets. Please clarify that the CO really wants a budget for the 2 regulatory activities for each contract year at double the effort?

Answer: The uniform budget assumptions for years 1 through 5 are for the purposes of developing a budget and do not necessarily reflect specific tasks to be accomplished. In accordance with the RFP, Appendix B, assume twice the effort of year one for years 2 through 5.

END OF AMENDMENT 2 TO RFP NIH-NIAID-DAIT-05-37