

§ 3403.8

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for Federal Government use, reserves the right to require the patentee to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 U.S.C. 205, USDA will not make public any information disclosing a USDA-supported invention for a four-year period. SBIR awardees must report inventions to the awarding agency within two months of the inventor's report to the awardee. The reporting of inventions shall be made through submission to Interagency Edison as specified in the terms and conditions of the grant.

(15) *Organizational management information.* Before the award of an SBIR funding agreement, USDA requires the submission of certain organizational management, personnel, and financial information to assure responsibility of the applicant. This information is not required unless a project is recommended for funding, and then it is submitted on a one-time basis only. However, new information should be submitted if a small business concern has undergone significant changes in organization, personnel, finance or policies, including those relating to civil rights.

(16) *Documentation of commercialization record of firms with multiple phase II awards.* A small business concern submitting a proposal for a Phase I award that has received more than 15 Phase II SBIR awards during the preceding five fiscal years must document the extent to which it was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards.

(b) [Reserved]

§ 3403.8 Proposal format for phase II applications.

(a) The following items relate to Phase II applications. Further instructions or descriptions for these items as well as any additional items to be included will be identified in the annual program solicitation as necessary. See § 3403.9.

(1) *SF-424 R&R cover sheet.* Follow instructions found in § 3403.7(a)(1).

(2) *Project summary.* Follow instructions found at § 3403.7(a)(2).

(3) *Phase I results.* The proposal should contain an extensive section that lists Phase I objectives and makes detailed presentation of the Phase I results. This section should establish the degree to which Phase I objectives were met and feasibility of the proposed research project was established.

(4) *Proposal.* Since Phase II is the principal research and development effort, proposals should be more comprehensive than those submitted under Phase I. However, the outline and information contained in § 3403.7(a)(3)–(9) and § 3403.7(a)(11)–(14) should be followed, tailoring the information requested to the Phase II project.

(5) *Cost breakdown on proposal budget.* For Phase II, a detailed budget is required for each year of requested support. In addition, a summary budget is required detailing the requested support for the overall project period. A budget narrative, with supporting budget detail for each budget category must be included.

(6) *Organizational management information.* Each Phase II awardee will be asked to submit an updated statement of financial condition (such as the latest audit report, financial statements or balance sheet) and report any changes in management or principals.

(7) *Commercialization Plan.* A succinct commercialization plan must be included in each SBIR Phase II proposal moving toward commercialization. Elements of a commercialization plan may include the following:

(i) *Company information.* Focused objectives/core competencies; size; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding; regulatory experience; and subsequent commercialization.

(ii) *Customer and competition.* Clear description of key technology objectives, current competition, and advantages compared to competing products or services; description of hurdles to acceptance of the innovation.

(iii) *Market.* Milestone, target dates, analyses of market size, and estimated market share after first year sales and after five years; explanation of plan to obtain market share.

(iv) *Intellectual property.* Patent status, technology lead, trade secrets or

other demonstration of a plan to achieve sufficient protection to realize the commercialization state and attain at least a temporary competitive advantage.

(v) *Financing*. Plans for securing necessary funding in Phase III.

(vi) *Assistance and mentoring*. Plans for securing needed technical or business assistance through mentoring, partnering, or through arrangements with state assistance programs, Small Business Development Centers, Federally-funded research laboratories, manufacturing extension Partnership Centers, or other assistance providers.

(8) *Data Collection*. Each Phase II applicant will be required to provide information to the Tech-Net Database System (<http://technet.sba.gov>) per OMB No. 3245-03356. The following are examples of the data to be entered by applicants into Tech-Net:

(i) Any business concern or subsidiary established for the commercial application of a product or service for which an SBIR award is made;

(ii) Revenue from the sale of new products or services resulting from the research conducted under each Phase II award;

(iii) Additional investment from any source, other than Phase I or Phase II awards, to further the research and development conducted under each Phase II award; and

(iv) Updates to information in the Tech-Net database for any prior Phase II award received by the small business concern.

(b) [Reserved]

Subpart D—Submission and Evaluation of Proposals

§ 3403.9 Submission of proposals.

The SBIR program solicitation for Phase I proposals and the correspondence requesting Phase II proposals will provide the deadline date for submitting proposals, and instructions for submitting the proposal to CSREES for funding consideration.

§ 3403.10 Proposal review.

(a) The receipt of all proposals will be acknowledged.

(b) All Phase I and II proposals will be evaluated and judged on a competi-

tive basis. Proposals will be initially screened to determine responsiveness. Proposals passing this initial screening will be technically evaluated by scientists to determine the most promising technical and scientific approaches. Each proposal will be judged on its own merit. USDA is under no obligation to fund any proposal or any specific number of proposals in a given topic. It also may elect to fund several or none of the proposed approaches to the same topic or subtopic.

(c) Phase I and II proposal evaluation criteria will be published in the "Method of Selection and Evaluation Criteria" section of the program solicitation.

(d) External peer reviewers may be used during the technical evaluation stage of this process. Selections will be made from among recognized specialists who are uniquely qualified by training and experience in their respective fields to render expert advice on the merit of proposals received. It is anticipated that such experts will include those located in universities, government, and nonprofit research organizations. If possible, USDA intends that peer review groups shall be balanced with minority and female representation and with an equitable age distribution.

(e) Reviewers will base their conclusions and recommendations on information contained in the Phase I or Phase II proposal. It cannot be assumed that reviewers are acquainted with any experiments referred to within a proposal, with key individuals, or with the firm itself. Therefore, the proposals should be self-contained and written with the care and thoroughness accorded papers for publication.

(f) Final decisions will be made by USDA based upon the rating assigned by reviewers in consideration of the technical and commercial potential of the application, duplication of research, any critical USDA requirements, resubmission and budget limitation. In the event that two or more proposals are of approximately equal merit, the existence of a cooperative research and development agreement (CRADA) with a USDA laboratory will