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Comptroller General
of the United States

United States Government Accountability Office
Washington, DC 20548

Decision

Matter of: DOR Biodefense, Inc.; Emergent BioSolutions

File: B-296358.3; B-296358.4

Date: January 31, 2006

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Scott N. Flesch, Esq., Department of the Army, and Eric Lile, Esq., Joint Program Executive Office for Chemical and Biological Defense, for the agency.
Jonathan L. Kang, Esq., and Michael R. Golden, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Protest that modification of contract for research and development of botulinum vaccine was outside scope of the original contract is denied where changes did not substantially alter the contract's type of work, costs or period of performance beyond that which could have been reasonably anticipated by offerors.

DECISION

DOR Biodefense, Inc. and Emergent BioSolutions protest the issuance of modification P00186 of contract No. DAMD17-98-C-8024 by the Department of the Army Space and Missile Command to DynPort Vaccine Company, LLC (DVC).[1] The protesters contend that the modification was beyond the scope of the original contract, and thus was an improper sole-source award to DVC. The protesters also contend that the agency failed to take reasonable corrective action in response to earlier protests concerning the modification.

We deny the protests.

[1] DVC is a limited liability company, in which DynCorp, a wholly-owned subsidiary of Computer Sciences Corporation (CSC), is the principal member. CSC participated in this protest as an intervenor.

BACKGROUND

The agency awarded a contract to DVC, under solicitation No. DAMD17-95-R-5020 (RFP) in 1997. The contract was issued by the Joint Vaccination Acquisition Program (JVAP), which was established in 1996 by the Department of Defense (DOD) to develop and stockpile biological defense vaccines for use by the U.S. military. Memorandum of Law at 1-2.

The JVAP issued the RFP in August 1996, seeking proposals for award of a contract to a prime systems contractor for the management of vaccine development, licensure and production efforts. Id. at 2. The contractor was required to "use information and materials from the existing DoD program to create and execute an integrated approach leading to FDA [Food and Drug Administration] licensure and long term production/stockpiling of each vaccine (life cycle management to the point of product release to the DoD distribution chain)." RFP at C-1. Offerors were required to propose a comprehensive technical approach to meeting DOD's biological defense needs. Offerors were required to propose an Integrated Master Plan (IMP) that described their approach to "the core activities and processes necessary to achieve the program objectives (i.e. the [statement of objectives])." RFP attach. 1, IMP Instructions, at 1. The RFP, however, did not specify particular technical approaches for vaccine development, but rather identified general process requirements and the types of biological threats that the agency could select for vaccine development and production.

The RFP listed contract line item numbers (CLINs) for general requirements such as systems integration, hazard risk insurance, storage and maintenance of intermediaries, and special studies, as well as development of three vaccines for protection against Q-fever, vaccinia, and tularemia. RFP at B-2. The RFP listed optional CLINs for development and licensure of biological warfare vaccines for the following vaccines: monovalent and multivalent botulinum serotypes, ricin, staphylococcal enterotoxin B, venezuelan equine encephalitis, combined Venezuelan/eastern/western equine encephalitis, brucellosis, plague, improved anthrax, and vaccinia immune globulin. Id. As relevant here, optional CLIN 0016 required development of a tetravalent botulinum vaccine for serotypes A, B, E and F.[2] Id. The RFP advised offerors that it reserved the right to "change the list above to add or delete products as the need may arise." RFP at B-1, C-1.

[2] A serotype refers to the specific form of a biological threat for which a vaccine is developed. Each serotype has an antigen that provokes a specific antibody response in the recipient. A vaccine's valence refers to the number of serotypes in the vaccine, e.g., a monovalent, bivalent, or multivalent vaccine. Contracting Officer's Statement at 11. A multivalent vaccine, therefore, protects against the multiple biological threats represented by its constituent serotypes.

All of the vaccines developed under the contract require approval and licensure by the FDA. RFP at C-1. The contractor bears the responsibility for submitting applications and ultimately obtaining FDA licensure for the vaccines; the contractor also becomes the license holder for the approved vaccine. Id. The RFP stated that contract performance would occur in stages based on various decisions made by the agency's Milestone Decision Authority. Memorandum of Law at 4; RFP at C-1. The milestone A (originally termed milestone I) determination would identify the vaccines to be developed and would approve a technical approach. RFP, SOO at 1. The milestone B determination would approve entry into the system development and demonstration phase. JVAP Statement at 7.[3] The RFP stated that the contract would be awarded with various cost reimbursement and fixed-fee CLINS. RFP at 1. Contract performance was anticipated for 10 years. RFP at 2.

The agency awarded the contract to DVC on November 7, 1997, with an award value of $321,673,935. AR, Tab 6, DVC Contract. During the course of contract performance, the agency and DVC experienced numerous delays and challenges involving changed regulatory requirements and technical issues. See Contracting Officer's Statement at 13-15; JVAP Statement at 10-13.

In August 1999, the agency exercised optional CLIN 0016 and directed DVC to develop an FDA-licensed pentavalent botulinum vaccine and added serotype C to the existing requirement for serotypes A, B, D, and F. AR, Tab 21, Modification P00021. The modification did not change the delivery date for CLIN 0016 of August 16, 2004, which had been established in DVC's proposal based on anticipated CLIN exercise dates and scheduled resource transfer assumptions identified in the RFP. Memorandum of Law at 12. Modification P00021 also requested that DVC submit a price proposal that would account for increased costs in CLIN 0016 resulting from the addition of serotype C to the multivalent vaccine requirement. AR, Tab 21, Modification P00021, at 2.

The agency issued modification P00033 in March 2000, which "zeroed out" the costs of individually developing the five monovalent vaccines that comprised the serotypes for the CLIN 0016 pentavalent vaccine, and incorporated DVC's price proposal, which had been requested under modification P00021. The value of CLIN 0016 was increased from [deleted] to [deleted].[4] JVAP Statement at 4.

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[3] This statement was filed by the JVAP Vaccine Manager as part of the agency's report to our Office, and supplements the Contracting Officer's Statement and the Memorandum of Law.

[4] As the agency explains, a monovalent vaccine is considered simpler to produce than a multivalent vaccine because the former involves only a single serotype, whereas the latter must combine various serotypes into a single multivalent vaccine. Contracting Officer's Statement at 11. Each of the monovalent botulinum vaccines under CLINs 0009-0015 was intended to be developed individually and then

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Due to concerns that sufficient funding was not available to fully develop the pentavalent vaccine, the agency determined in March 2001 that the program should focus on the "highest threat," and develop a bivalent vaccine for serotypes A and B instead of the pentavalent vaccine. Memorandum of Law at 14-15; AR, Tab 38, Acquisition Decision Memorandum, March 21, 2001.

Additionally in 2001, the agency executed several modifications to account for increased costs, including changes in FDA regulations and recommendations, technology transfer requirements, changed travel and labor costs, manufacturing facility changes, and additional studies which increased CLIN 0016's price by approximately [deleted] to [deleted]. See AR, Tab 41, Modification P00055; Tab 44, Modification P00056; Tab 46, Modification P00060; Tab 50, Modification P00070; Tab 54, Modification P00071; Tab 52, Modification P00075; Tab 56, Modification P00084; Tab 51, Modification P00085; Tab 59, Modification P00089; Tab 60, Modification P00090; Tab 61, Modification P00092; Tab 63, Modification P00099; and Tab 68, Modification P00112.

During the 1999-2001 timeframe, the agency also determined that the original target date of 2004 for delivery of licensed vaccines under CLIN 0016 was no longer realistic. Contracting Officer's Statement at 16. In 2001, the agency requested and DVC proposed a revised delivery date of 2012 for a FDA-licensed botulinum serotype A/B vaccine, at an estimated overall cost of [deleted]. AR, Tab 45, IMP 2.0. The agency issued modification P00059 in August 2001, which specified a new delivery date of July 2012. Memorandum of Law at 17; AR, Tab 49, Modification P00059, at 2.

In January 2004, DVC submitted its proposal for IMP 5.0 in response to the agency's request that DVC address and summarize the current approach to developing the serotype A/B vaccine. AR, Tab 95, DVC IMP 5.0. The agency issued modification P00153 on May 20, 2004, which incorporated IMP 5.0, and stated that the final costs and delivery date would be determined at a later date. The changes to the cost and delivery schedule were established in modification P00186 on April 7, 2005, which

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individual serotypes would be combined into a multivalent vaccine under CLIN 0016. Id. The cost of CLIN 0016 was less than any of the monovalent vaccines, however, because it was assumed that all of the individual monovalents would have been produced under separate CLINs prior to the development of the multivalent vaccine. Id.; see also AR, Tab 2, DVC Best and Final Proposal, at K-1. Thus when the agency deleted the requirements for the individual monovalent vaccines and "zeroed out" the funding under CLINs 0009, 0010, 0011, 0013, and 0014, the value of CLIN 0016 was increased to reflect the fact that separate funding would no longer be provided under the deleted CLINs for the required development of the individual monovalent vaccines.

contained a delivery date of May 6, 2012, and increased the costs of CLIN 0016 to $192,276,758. AR, Tab 121, Modification P00186.

During the same early 2004 period of time, the agency issued a request for information (RFI) as part of the Milestone B approval process. The Milestone B evaluation required the agency to conduct market research regarding alternatives to the current technical approach under the contract. JVAP Statement at 7. The agency issued the RFI on February 25, 2005, seeking responses from offerors regarding the availability of alternative botulinum vaccine candidates for purposes of "analyzing alternatives to its current recombinant botulinum effort in preparation for an acquisition decision to enter into the System Development and Demonstration Phase of product development." AR, Tab 112, RFI, at 1. The RFI informed potential respondents that "[t]his is a request for information only; no contract will result from responses received for this RFI . . . This is not a Request for Proposal, an Invitation to Bid, or a Request for Quotation. Therefore, this RFI is not to be construed as a commitment by the Government to enter into a contract nor will the Government pay for information provided in response to this RFI." Id.

DOR and Emergent each submitted responses to the RFI. The agency posted a notice on the FedBizOpps website on April 20, 2005 regarding issuance of modification P00186. Emergent and DOR each filed protests of the modification, arguing that P00186 exceeded the scope of the original contract and was thus an improper sole-source award that should have been subject to full and open competition. In May 2005, the agency requested that our Office dismiss the protests based on its determination to take corrective action; we did so on May 20.

In June 2005, as part of its corrective action, the agency issued a synopsis of its intent to modify DVC's contract and requested responses from firms that could demonstrate alternatives to DVC's vaccine candidate. The protesters each submitted responses regarding their capabilities. The agency then concluded that the modification was within the scope of the original contract, and that therefore a sole-source justification was not required. After receiving notice of the agency's determination, DOR and Emergent filed these protests.

DISCUSSION

Scope of the Modification

The protesters first argue that modification P00186 exceeded the scope of the original contract, and that it therefore constituted an improper sole-source award under the Competition in Contracting Act of 1984 (CICA), 10 U.S.C. § 2304(a)(1)(A)

(2000), which was required to be competed on a full and open basis.[5] Once a contract is awarded, our Office will generally not consider protests against modifications to that contract, because such matters are related to contract administration and are beyond the scope of our bid protest function. Bid Protest Regulations, 4 C.F.R. § 21.5(a) (2005); Engineering & Prof'l Servs., Inc., B-289331, Jan. 28, 2002, 2002 CPD ¶ 24 at 4. An exception to this general rule is where, as here, a protester alleges that a contract modification is beyond the scope of the original contract, because, absent a valid sole-source determination, the work covered by the modification would be subject to the statutory requirements for competition. Atlantic Coast Contracting, Inc., B-288969.4, June 21, 2002, 2002 CPD ¶ 104 at 4.

In determining whether a modification triggers the competition requirements under CICA, we look to whether there is a material difference between the modified contract and the contract that was originally awarded. Engineering & Prof'l Servs., supra, at 4; see AT&T Communications, Inc. v. Wiltel, Inc., 1 F.3d 1201, 1205 (Fed. Cir. 1993). Evidence of a material difference between the modification and the original contract is found by examining changes in the type of work, costs, and performance period between the contract as awarded and as modified. MCI Telecomms. Corp., B-276659.2, Sept. 29, 1997, 97-2 CPD ¶ 90 at 7-8. We also consider whether the solicitation for the original contract adequately advised offerors of the potential for the type of change found in the modification, and thus whether the modification would have changed the field of competition. Id.

The contract contained the changes clause at FAR § 52.243-1, "Changes -- Fixed Price" and FAR § 52.243-2, "Changes -- Cost Reimbursement," both of which were incorporated with the "Alternate V" provisions for research and development contracts. The agency contends that these clauses provide the authority to modify the contract, and that the modification was within the scope of the contract as originally competed and awarded. As explained below, we believe that the record demonstrates that scope of the original contract was not substantially changed by the modification, and thus the changes to the contract would not have had a substantial impact on the field of competition for the original contract award.

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[5] The protesters' initial and current protests addressed the changes to the contract resulting from modification P00186. The protesters' comments on the agency report now suggest that prior modifications may also have been improper. Even assuming that the agency report is the first time the protesters became aware of the earlier modifications, the protesters' comments could not have raised any new timely grounds of protest because they were filed more than 10 days following receipt of the agency report, as the result of an extension the protesters requested for filing their comments. See Hyperbaric Techs., Inc., B-293047.4, Mar. 29, 2004, 2004 CPD ¶ 89 at 9, n.7. This decision thus addresses only whether modification P00186 was within the scope of the original competition and contract.

The protesters argue that the contract was improperly modified to require delivery of a bivalent serotype A/B vaccine, a product that was not listed among the optional RFP CLINs. The RFP identified optional CLINS for monovalent vaccine serotypes A through G, and a multivalent vaccine for serotypes A, B, D and F. RFP at B-1. The RFP advised offerors, however, that "[t]he government reserves the right to change the list above to add or delete products as need may arise." RFP at B-1.

Where the type of work under a contract as modified remains substantially unchanged, we do not view modifications of the technical requirements of performance to be outside the scope. Atlantic Coast, supra. Our decisions have acknowledged that additional latitude for changing a contract may exist where the contract is for research and development, noting that the scope of such contracts is often flexible because of unanticipated changes due to the lack of definitiveness of the government's requirements. Everpure, Inc., B-226395, B-226395.4, Oct. 10, 1990, 90-2 CPD ¶ 275 at 4-5. Furthermore, a technical change to a contract should be viewed in the context of the contractor's obligations "as a whole." AT&T Communications, Inc., 1 F.3d at 1206.

Here, the RFP made clear that decisions regarding the specific vaccines to be developed and produced would be made after award, and that the agency could add or delete vaccines based on the government's needs. RFP at B-1. The RFP and contract, in our view, anticipated addition and deletion of optional botulinum vaccines, and thus the change from the RFP's requirement under CLIN 0016 for a pentavalent vaccine to a bivalent vaccine that incorporates two of the serotypes under the pentavalent vaccine does not fundamentally alter the type of work required under the contract. See Engineering & Prof'l Servs., supra.

The protesters next argue that the modified contract now requires an increased number of troop equivalent doses (TED) of the botulinum serotype A/B vaccine to be produced. The RFP stated that an "initial stockpile" of 300,000 TED would be required for production of each vaccine, and that follow-on and production contracts will be awarded after FDA licensure of those vaccines. RFP at C-1, F-1.

At the agency's request, DVC drafted IMP 5.0 to increase the assumption for future production of the serotype A/B vaccine developed under CLIN 0016 from 300,000 to [deleted] TED.[6] AR, Tab 95, IMP 5.0, at 5-6. Modification P00186 incorporated IMP 5.0. See AR, Tab 121, Modification P00186 at 2. The agency states, however, that the increased TED amount was for planning purposes only, noting that CLIN 0016 is for the development, licensure and delivery of an FDA-licensed serotype A/B vaccine, and that CLIN 0052 covers production of the licensed vaccine. See

[6] IMP 5.0 notes that although the agency initially discussed an increase in TED amounts of [deleted] to [deleted], the agency and DVC subsequently agreed that the IMP would assume a production level of [deleted] TED. AR, Tab 95, IMP 5.0, at 6.

Supplemental Memorandum of Law at 4-5. CLIN 0052 will not be exercised until the vaccine is licensed. Id.

The modification detailed the modified costs related to "development and licensure" of the serotype A/B vaccine, but did not include any costs for production of the licensed vaccine. See AR, Tab 121, Modification P00186 at 2. Thus, modification P00186 did not commit the agency to production of the serotype A/B vaccine under either the original or the revised TED assumption levels. In the absence of an actual commitment under the contract, we do not believe that the proposed or planned change to TED assumptions under an unexercised CLIN affects the scope of the original contract at this time.[7] In sum, we do not believe that the technical changes discussed above constitute material changes to the scope of the original contract.[8]

Further, we conclude that the solicitation for the original contract adequately advised offerors of the potential for the type of changes that occurred during the course of contract performance, and that in the context of the type of research and development work at issue here, the modification encompasses changes which potential offerors could reasonably have anticipated. The RFP advised offerors that successful contract performance faced numerous challenges, including regulatory requirements: "The number of different medical [biodefense] products under this contract presents significant challenges in management, regulatory affairs, and

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[7] Additionally, the protesters do not consider the impact of the deletion of the individual CLIN requirements for the development of monovalent botulinum vaccines for serotypes A through G on the scope of the TED production requirements. Although the assumptions for future production of the serotype A/B vaccine has increased to [deleted] TED for CLIN 0016, the deletion of funding for the 5 monovalent vaccine CLINS that comprise the pentavalent vaccine presumably means that the production CLINs for those vaccines, CLINs 0045, 0046, 0047, 0049 and 0050, each of which had the same [deleted] TED initial stockpile amount, are also deleted, resulting in a [deleted] TED decrease.

[8] The protesters also contend that the agency modified CLIN 0016 to require development of the botulinum vaccine based on a recombinant technique, instead of a [deleted] technique. As the agency explains, however, offerors were not required to follow a specific technical approach in developing the optional botulinum vaccine option and the contract did not require a [deleted] approach. See RFP at B-1, C-2. Rather, as the protesters acknowledge, the RFP allowed either a [deleted] or recombinant approach to developing botulinum vaccines. Protesters' Supplemental Comments at 11. Furthermore, DVC's proposal did in fact propose development of the A and B serotype monovalent vaccines and the multivalent vaccine based on a recombinant approach. AR, Tab 2, DVC Best and Final Offer, at D-1, E-1, and K-1. Thus, the decision to pursue a recombinant approach provides no basis to support the protests.

production." RFP at C-2. Offerors were further advised that the prior development efforts had faced difficulties and the agency viewed the contract as a long-term effort:

> Licensure of [biodefense vaccine] products, however, has been problematic because of the lack of integration, required by the FDA, between the manufacturing process and product testing and evaluation (T&E) . . . The contract is based on the fact that FDA licensure of biologics is a long term process that requires extensive [testing and evaluation] of vaccines as the manufacturing process is scaled up from laboratory production to full scale production.

RFP at C-1.

We believe that the changes discussed above could have been reasonably anticipated by offerors, in light of the type of the work at issue, and the RFP's broad scope and statements regarding the technical and regulatory challenges that could affect performance. Engineering & Prof'l Servs, supra, at 4.

With regard to the changes to the cost of the contract under modification P00186, which the protesters also argue is not within the scope of the original contract, the agency contends that all changes were within the original contract's scope, which the agency emphasizes was a research and development contract with a broadly-defined mission of addressing the development of the government's biodefense needs. In executing the modification, the agency explained that "[t]he need for the new IMP [5.0] was driven by [FDA] and technical requirements unknown at the time of award."[9] AR, Tab 121, Modification P00186, at 2.

The modification increased the costs of CLIN 0016 by approximately $183 million, a 57 percent increase over the original contract value of $322 million.[10] In modification

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[9] The agency notes that more than 50 guidance documents and regulatory revisions have been published by FDA in the Federal Register during the performance period that have had an impact on contract costs. JVAP Statement at 10; Memorandum of Law at 29. The agency report contains numerous examples of FDA guidance, regulatory changes and specific interactions with the JVAP program. See AR, Tabs 7-13, 15-16, 19-20, 22, 24-27, 29, 31-34, 36, 39-40, 43, 47-48, 53, 57-58, 62, 64-65, 67, 70-73, 76-77, 79-91, 93-94, 100-105, 107, 110-11, 113-17, 119-20, 126, and 129-31.

[10] An alternative measure of the increase in CLIN 0016 would measure the value that modification P00186 added to the pre-modification value of CLIN 0016. This results in a significantly lower percentage increase of approximately 29 percent. Our decisions have recognized that prior increases to a contract that have not been challenged may properly be taken into account when subsequent contract modifications are challenged as out of scope. See Access Research Corp., B-281807,

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P00186, the agency identified 18 new or modified areas of work that have changed since the award of the contract. Id. at 4-7. The modification also details the cost impact of the changes required by the work. Id. at 8-17. The agency argues that the "most significant change" in FDA regulations that affected modification P00186 was the final issuance of the "Animal Rule" in 2002, which governs the testing of vaccine candidates on human surrogates. AR, Tab 121, Modification P00186, at 3. The RFP advised offerors that "[t]he nature of a [biological warfare agent] precludes human efficacy testing; and, therefore, will require surrogate models for licensure." RFP at C-1. The agency states that the FDA surrogate testing requirements were accurately stated in the RFP at the time of its issuance and that DVC's proposal adequately addressed those requirements, but that the Animal Rule required revisions to the work.[11] JVAP Statement at 10. The agency explains that FDA's final version of the Animal Rule "has significantly increased the number of animal studies required to license biodefense vaccines," and FDA has "increased the scope of studies or added more unplanned studies, . . . increased the number of volunteers required in clinical trial, have made the enrollment criteria more conservative so that fewer of the screened candidates are eligible to participate, . . . [and] added new requirements for toxicity testing." AR, Tab 121, Modification P00186, at 3.

The agency has, in our view, reasonably explained the basis for the increased costs under modification P00186, and supported its position that these costs constitute work within the scope of the contract. We further believe that the cost changes themselves are not so large as to render the modification outside the scope of the original contract. In this regard, even substantial increases in cost do not inexorably compel a conclusion that a contract has been modified outside its original scope. See, e.g., Defense Sys. Group; Warren Pumps, Inc.; Dresser Indus., Inc., B-240295 et al., Nov. 6, 1990, U.S. Comp. Gen. LEXIS 1182 at *11-13 (increase in value of more than 120% did not materially change the contract based on in-scope changes to technical requirements); Caltech Servs. Corp., B-240726, B-240726.6, Jan. 22, 1992,

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Apr. 5, 1999, 99-1 CPD ¶ 64 at 5. As discussed above, however, we believe that neither a 57 nor a 29 percent cost increase was outside the scope of the original contract under the circumstances of this procurement.

[11] The protesters argue that changes to FDA's Animal Rule should have been anticipated by offerors and the agency as the result of discussions between FDA, DoD and industry representatives as early as 1996. Protesters' Supplemental Comments at 4-5. Thus, the protesters contend, the changes cited by the agency should have been anticipated in DVC's proposal and the contract, and therefore the changes to the Animal Rule could not be a justification for increased costs. The final rule, however, was not published until May 31, 2002, almost five years after contract award. AR, Tab 64, 64 Fed. Red. 53960. The protesters fail to demonstrate that the final form of the rule, as issued by FDA, could have been known and incorporated into offerors' cost and technical proposals prior to issuance of the final rule in 2002.

92-1 CPD ¶ 94 (30 percent overall increase in CLIN value not out of scope where the overall contractual purpose remains unchanged).

The protesters also argue that the modification of the delivery date increases the duration of the contract beyond the scope of the original contract. The RFP stated that the agency anticipated a performance period of 10 years, and noted that exercise of optional CLINs would not increase this 10 year period. RFP at 2; RFP amend. 2, Question and Answer 6. The contract included DVC's delivery date of August 2004 for delivery of the multivalent botulinum vaccine under CLIN 0016, based on the expected CLIN exercise date identified in the RFP. JVAP Statement at 3. As modified by P00186, DVC is now required to provide the serotype A/B vaccine by May 2012.

Although we look to the performance period to determine whether a modification exceeds the scope of the original contract, time does not have the same degree of importance in every type of contract. Where, as here, a contractor is provided additional time to perform a contractual obligation, that modification does not necessarily constitute an out of scope change, unlike the situation where time is used to define the extent of the obligation, such as under a requirements contract. Defense Sys. Group, supra. Additionally, as discussed above, our decisions have recognized that research and development contracts can justify additional latitude for changes to their performance terms, including duration, because the type of work under these contracts involves greater uncertainty. Ion Track Instruments, Inc., B-238893, July 13, 1990, 90-2 CPD ¶ 31 at 3.

We recognize that modification P00186 has substantially increased the costs and duration of CLIN 0016. However, we believe that the modification did not materially change the contract because, as discussed above, the changes to the type of work, costs, and duration of the contract remain within the scope of the original contract. See Atlantic Coast Contracting, supra, at 4. Furthermore, the changes could have been reasonably anticipated by offerors, given the complexity of the research and development work and the risks and contingencies identified in the solicitation. Id.

The protesters' comments and supplemental comments also generally argue that the entire contract has been plagued with problems and that the procurement will fail. See Protesters' Comments at 6, 16-17. The protesters criticize what they believe to be technical flaws in the DVC vaccine candidate as compared to what they characterize as superior DOR or Emergent alternative products. We do not believe that challenges to the efficacy of DVC's technical approach or the contract generally are relevant to the issue that was timely protested, i.e., whether modification P00186 was within the scope of the original contract.[12]

[12] We have reviewed all of the remaining issues raised by the protesters regarding modification P00186, and conclude that they are without merit or not for our review.
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Adequacy of Prior Corrective Action

Finally, the protesters contend that the agency did not take adequate or reasonable corrective action in response to their initial protests challenging the propriety of the modification. The protesters argue that the agency acted in bad faith by not taking the corrective action it outlined in its request to dismiss the initial protests. The agency's letter to our Office requesting that the initial protests be dismissed stated that the agency did not agree with the protesters' contentions that the modification constituted a sole-source award. AR, Tab 128, Agency Corrective Action Memorandum, at 1. Nonetheless, the agency determined that it would take corrective action by reviewing its requirements and making a new determination as to how best to meet its needs. Id. The agency stated that it would issue a synopsis to "appraise all prospective sources of the agency's needs so that those sources have a meaningful opportunity to demonstrate their ability to meet our requirements," and that the agency would evaluate responses and "make a determination concerning whether a sole-source award is justified." Id.

Following our dismissal of the protest, the agency posted the June 2005 synopsis on the FedBizOpps website, detailing the agency's intention to "modify contract DAMD17-98-C-8024 and negotiate on a sole-source basis with [DVC] to extend the development and licensure period of performance to May 2012." AR, Tab 132, Agency Synopsis, June 1, 2005, at 1. The synopsis advised that "[t]his is not a request for competitive proposals but parties purporting to have the requisite credentials to perform these services without substantial duplication of cost or unacceptable delays in fulfilling the agency's requirements" may submit responses detailing their capabilities. Id.

Each protester submitted a response to the agency's notice, renewing their objections to the modification of DVC's contract and outlining their respective qualifications to provide an alternative vaccine candidate. The agency's subsequent notice to the protesters did not address their capabilities, but rather explained that the agency had determined that the modification was within the scope of the original contract, and that it would not, therefore, issue a sole-source award or justification thereof. AR, Tabs 126-37, Agency Notices Regarding Corrective Action, at 1.

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For example, the protesters allege that modification P00186 violates the Anti-Deficiency Act, 31 U.S.C. § 1341, which prohibits agencies from entering into contract obligations in excess of current appropriations or obligations prior to the appropriation of funds. Because we conclude that the modification was within the scope of the original contract and did not result in a new contract award, this protest allegation pertains to a matter of contract administration, which our Office does not review in the context of a bid protest. 4 C.F.R. § 21.5(a).

Contracting officials have broad discretion to take corrective action where the agency determines that such action is necessary to ensure fair and impartial competition. Patriot Contract Servs. LLC et al., B-278276.11 et al., Sept. 22, 1998, 98-2 CPD ¶ 77 at 4. Where an agency has reasonable concerns that there were errors in the procurement, the agency may take corrective action, even if it is not certain that a protest of the procurement would be sustained. Main Bldg. Maint., Inc., B-279191.3, Aug. 5, 1998, 98-2 CPD ¶ 47 at 3. We will not object to the specific proposed corrective action, so long as it is appropriate to remedy the concern that caused the agency to take corrective action. Networks Elec. Corp., B-290666.3, Sept. 30, 2002, 2002 CPD ¶ 173 at 3. Corrective action does not require, however, that the agency take actions favorable to the protester and there is no basis to object if the agency ultimately reaches the same conclusion that was challenged in the original protest, provided that the corrective action was undertaken in good faith and the reaffirmed conclusion has a reasonable basis.

We believe that the agency properly exercised its discretion to take corrective action in response to the protest. While it is not entirely clear to what extent the agency evaluated the protesters' responses, which primarily objected to the agency's actions, the agency ultimately determined that neither a sole-source nor a competitive award was required because the modification, as originally issued, was within the scope of the contract. We do not read the agency's memorandum outlining its proposed corrective action to commit the agency to either award a competitive contract or issue a sole-source award. Although the agency's synopsis used the term "sole-source," we do not think that the use of this term, particularly in the context of the notice's intent to modify the contract, committed the agency to issue a sole-source contract. In this regard, determining that a sole-source award is not required is not inconsistent with the agency's determination to "make a determination concerning whether a sole-source award is justified." AR, Tab 128, Agency Corrective Action Memorandum, at 1. We conclude that there is no support for the protesters' allegations of bad faith regarding these actions.[13]

The protests are denied.

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General Counsel

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[13] Additionally, because we deny the protests on the merits, there was no potential prejudice to the protesters regarding this matter. See McDonald Bradley, B-270126, Feb. 8, 1996, 96-1 CPD ¶ 54 at 3; see Statistica, Inc. v. Christopher, 102 F.3d 1577, 1581 (Fed. Cir. 1996). Notwithstanding the protesters' disagreement over the form and timing of the agency's corrective action, the protesters have had an opportunity to challenge the modification on the merits, and cannot demonstrate that they were harmed in any way related to the corrective action.