Exhibit D

Siri | Glimstad

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CDC FREEDOM OF INFORMATION ACT APPEAL

SUBMITTED VIA EMAIL October 17, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: *Appeal of FOIA Request #23-00363-FOIA (IR#0971A)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, on December 8, 2022, we submitted the following request for records ("**FOIA Request**") from the files of the Centers for Disease Control and Prevention (the "**Agency**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"):

> All communications sent or received by Contracting Officer Representative Traci S. Roberts from August 27, 2020 through the date of the search concerning Contract 47QTCK18D0003 Task Order 75D30120F09621.

(**Attachment 1**.)

The request was acknowledged and assigned FOIA Request #23-00363-FOIA on December 13, 2022. (**Attachment 2**.)

On August 7, 2023, the Agency responded to the FOIA Request ("**Final Response**"). The letter stated in relevant part:

> We located 957 pages of responsive records (702 pages released in full or part; 255 pages withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemptions 4, 5, & 6. The foreseeable harm standard was considered when applying these redactions.

> Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. We have determined that the information withheld is customarily and actually kept private and confidential by the submitter of the information. . . .
>
> Information withheld under [Exemption 5] was protected under the deliberative process privilege. . . . The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include internal emails. . . .
>
> The information that has been withheld under Exemption 6 consists of personal information, such as medical information. We have determined that the individual(s) to whom this information pertains has a substantial privacy interest in withholding it.

(**Attachment 3**.)

ICAN writes now to appeal the Final Response.

A. Argument

For the reasons set forth below, ICAN appeals the Agency's Final Response:

1. The Agency Improperly Withheld Records Under FOIA Exemption 4

a. Legal Standard

The Agency has not properly demonstrated that the withheld records fall under the scope of Exemption 4. "An agency withholding responsive documents from a FOIA release bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011). Exemption 4 prevents disclosure of "trade secrets and commercial or financial information obtained from a person and privileged or confidential[.]" 5 U.S.C. § 552(b)(4). The exemption applies to two categories of information. *Nw. Coal. for Alts. to Pesticides v. Browner*, 941 F. Supp. 197, 201 (D.D.C. 1996). The first category, "trade secrets," applies to "'a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.'" *Id.* at 201-202 (quoting *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983)).

The second category is "[i]nformation that (1) is financial or commercial; (2) was obtained from a person; and (3) is privileged or confidential[.]" *Id.* at 202. "[I]nformation is commercial under this exemption if, in and of itself, it serves a commercial function or is of a commercial nature." *Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 38 (D.C. Cir. 2002). In other words, "records that actually reveal basic commercial operations, such as sales statistics, profits and losses

and inventories, or relate to the income-producing aspects of a business" fall within the scope of commercial information. *Public Citizen Health Research Group*, 704 F.2d, at 1290.

Commercial or financial information is "confidential" for the purposes of Exemption 4 when it is "both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy." *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019). However, provided the narrow construction given to FOIA exemptions, courts have cautioned that "[n]ot every bit of information submitted to the government by a commercial entity qualifies for protection under Exemption 4." *Public Citizen Health Research Group*, 704 F.2d at 1290. An agency must reasonably demonstrate that the private owner of the records treats the information as "confidential." *See Ruston v. DOJ*, 521 F. Supp. 2d 18, 18-21 (D.D.C 2007)

Additionally, to carry its burden, the agency must demonstrate that "the agency reasonably foresees that disclosure would harm an interest protected by an exemption" or if disclosure is "prohibited by law." 5 U.S.C. § 552(a)(8)(A). "Conclusory and generalized allegations of substantial competitive harm, of course, are unacceptable and cannot support an agency's decision to withhold requested documents." *Public Citizen Health Research Group,* 704 F.2d at 1291. In the context of information withheld under Exemption 4, an agency satisfies the foreseeable harm requirement by demonstrating "foreseeable commercial or financial harm to the submitter upon release of the contested information." *Seife v. United States Food & Drug Admin.*, 43 F.4th 231, 241-42 (2d Cir. 2022).

Lastly, FOIA requires that "[a]ny reasonably segregable portion of a record . . . be provided to any person requesting such record after deletion of the portions which are exempt under [subsection b]." 5 U.S.C. § 552(b). "To withhold records, then, the agency must establish that an exemption applies and, for mixed requests, must still disclose 'all reasonably segregable, nonexempt portions of the requested record(s).'" *Elec. Privacy Info. Ctr.*, 910 F.3d at 1237 (quoting *Assassination Archives & Research Ctr. v. CIA*, 334 F.3d 55, 57-58 (D.C. Cir. 2003)). The government has the "burden of demonstrating that no reasonably segregable information exists within . . . documents withheld." *Loving v. DOD*, 550 F.3d 32, 41(D.C. Cir. 2008).

b. Application of Legal Standard

The Agency has failed to prove the applicability of Exemption 4 for three reasons. First, the Agency did not explain how the withheld information qualifies as a trade secret or confidential commercial or financial information. *Nw. Coal. for Alts. to Pesticides*, 941 F. Supp. at 201. Instead, the Agency's Final Response, in relevant part, stated:

> Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. We have determined that the information withheld is customarily and actually kept private and confidential by the submitter of the information.

(**Attachment 3**.)

Stating that portions of the requested records satisfy the criteria for withholding records under Exemption 4, does not adequately explain *how* the withheld portions qualify as a trade secret or confidential commercial or financial information.

In fact, the information withheld by the Agency does not appear to be confidential information within the meaning of Exemption 4. For example, the Agency withheld the names and email addresses of the General Dynamics Information Technology ("**GDIT**") employees working on the contract on pages 52-59, 110-111, 112-113, 372-373, 381, 382-383, 396-400, 401, 407-415, 434-436, and 437-438 in Part 1 of the production, and pages 96-108, 194-206, 281, 319-322, 349-352, 438-459, and 460 in Part 2. Similarly, the Agency employed Exemption 4 to withhold the number of VAERS reports submitted and processed by GDIT employees on pages 51-56, 112-113, and 407-415 of Part 1 of the production. This information is not confidential information and should not have been withheld under Exemption 4.

Second, the Agency's Final Response did not establish how disclosure of the withheld information is likely to cause substantial harm. *Seife*, 43 F.4th at 241-42. The Agency's Final Response stated that "The foreseeable harm standard was considered when applying [the] redactions." (**Attachment 3**.) However, simply stating that the Agency considered the foreseeable harm standard does not adequately explain *how* disclosure of the withheld information is likely to cause harm.

Lastly, the Agency did not demonstrate that there is no reasonably segregable information within the withheld portions of the production. *Loving*, 550 F.3d at 41. The Agency employed Exemption 4 to withhold large swaths of records throughout the production. For example, see the redactions on pages 57, 110, 374-375, 412-415, and 459-460 in Part 1 of the production and pages 176, 177-189, and 349-351 in Part 2. The Agency's Final Response does not mention the segregability of these records. (**Attachment 3**.) The Agency's failure to indicate whether all segregable portions have been disclosed combined with the Agency's blanket use of Exemption 4 suggests segregable information may exist withing the withheld records.

For these reasons, the Agency has failed to prove the applicability of Exemption 4. ICAN requests the Agency either prove the applicability of Exemption 4 and indicate whether all reasonably segregable portions of the requested records have been disclosed or promptly provide ICAN with an unredacted copy of the requested records.

2. The Agency Improperly Withheld Records Under FOIA Exemption 5

a. Legal Standard

The Agency has not properly demonstrated that the withheld records fall under the scope of Exemption 5. "Exemption 5 claims must be supported with specificity and [in] detail." *Judge Rotenberg Educ. Ctr., Inc. v. United States FDA*, 376 F. Supp. 3d 47, 65 (D.D.C. 2019) (citations omitted). The document must be: (1) an inter-agency or intra-agency document; (2) "predecisional"; and (3) deliberative. *Tigue v. United States DOJ*, 312 F.3d 70, 76 (2nd Cir. 2002). The Supreme Court has defined 'predecisional' records as those records "prepared in order to assist an agency decision maker in arriving at his decision." *Renegotiation Bd. v. Grumman Aircraft*

Eng'g Corp., 421 U.S. 168, 184 (1975). Documents are deemed to be deliberative if "they were prepared to help the agency formulate its position." *Fish & Wildlife Serv*., 141 S. Ct. 777, 786, 209 L. Ed. 2d 78 (2021). "This standard requires the agency to explain (i) "the nature of the specific deliberative process involved," (ii) "the function and significance of the documents in that process," and (iii) "the nature of the decisionmaking authority vested in the document's author and recipient." *Brennan Ctr. for Justice at NY Univ. Sch. of Law v. Dep't of Homeland Sec*., 331 F. Supp. 3d 74, 93-94 (S.D.N.Y. 2018).

Additionally, to carry its burden, the agency must demonstrate that "it is reasonably foreseeable that release of those materials would cause harm to an interest protected by that privilege." *Reporters Comm. for Freedom of the Press v. FBI,* 3 F.4th 350, 361 (D.C. Cir. 2021) (citing *Machado Amadis v. U.S. Dep't of State*, 971 F.3d 364, 370 (D.C. Cir. 2020) (emphasis added); 5 U.S.C. § 552(a)(8)(A)(i)(I)). "In the context of withholdings made under the deliberative process privilege, the foreseeability requirement means that agencies must concretely explain how disclosure 'would'– not 'could'– adversely impair internal deliberations." *Reporters Comm. for Freedom of the Press,* 3 F.4th. at 369-70 (quoting *Machado Amadis*, 971 F.3d at 371).

Even if the deliberative process privilege applies, it "does not protect documents in their entirety; if the government can segregate and disclose non-privileged factual information within a document, it must." *Nat'l Day Laborer Org. Network v. United States Immigration & Customs Enf't*, 486 F. Supp. 3d 669, 689 (S.D.N.Y. 2020) (quoting *Loving*, 550 F.3d at 38). "Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection." 5 U.S.C. § 552(b). Only factual material that is "inextricably intertwined with exempted portions" of the documents need not be disclosed. *Johnson v. Exec. Office for U.S. Attorneys*, 310 F.3d 771, 776 (D.C. Cir. 2002). The government has the "burden of demonstrating that no reasonably segregable information exists within . . . documents withheld." *Loving*, 550 F.3d at 41. "[T]he ultimate objective of exemption 5 is to safeguard the deliberative process of agencies, not the paperwork generated in the course of that process." *Nat'l Wildlife Fed'n v. U.S. Forest Serv*., 861 F.2d 1114, 1119 (9th Cir. 1988).

b. Application of Legal Standard

The Agency has failed to prove the applicability of Exemption 5 for four reasons. First, the Agency has not provided the specificity and detail required to withhold records under Exemption 5. *Judge Rotenberg Educ. Ctr., Inc.*, 376 F. Supp. 3d at 65. Instead of providing the specificity and detail that FOIA requires, the Agency's Final Response, in relevant part, stated:

> The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include internal emails.

(**Attachment 3**.)

The Agency's Final Response did not explain how the withheld information qualifies as inter-agency or intra-agency. *Tigue*, 312 F.3d at 76. Some of the redacted emails are not inter-agency or intra-agency communications because they were shared with non-agency personnel. For example, the Agency employed Exemption 5 to withhold portions of the emails on pages 372 and 410 in Part 1 of the production and pages 205, 321 and 460 in Part 2; however, these emails were shared with non-agency personnel. Specifically, the emails on these pages were shared with various personnel from GDIT. Therefore, these emails are not inter-agency or intra-agency communications and are not subject to Exemption 5.

Second, the Agency's Final Response did not explain how the withheld information qualifies as predecisional and deliberative. *Tigue*, 312 F.3d at 76. The Agency's Final Response did not explain the nature of the deliberative process involved, the function and significance of the information withheld under the deliberative process, or the nature of the decision-making authority vested in the information's author and recipient. *Brennan Ctr. for Justice at NY Univ. Sch. of Law*, 331 F. Supp. 3d at 93-94.

Third, the Agency's Final Response did not explain how it is reasonably foreseeable that the release of the withheld information would adversely impair the Agency's internal deliberations. *Reporters Comm. for Freedom of the Press*, 3 F.4th. at 369-70. The Agency's Final Response stated that "The foreseeable harm standard was considered when applying [the] redactions." (**Attachment 3**.) Stating that the Agency considered the foreseeable harm standard does not concretely explain *how* disclosure would adversely impair internal deliberations.

Lastly, it appears the Agency failed to segregate and release nonexempt factual information. The Agency employed Exemption 5 to withhold large swaths of records within the production. For example, see the redactions on pages 372 and 403 in Part 1 of the production and pages 321, and 338-343 in Part 2. The Agency's Final Response does not mention the segregability of these portions of records. (**Attachment 3**.) The Agency's failure to indicate whether all segregable portions have been disclosed suggests segregable information may exist withing the withheld documents.

For these reasons, the Agency has failed to prove the applicability of Exemption 5. ICAN requests, the Agency prove the applicability of Exemption 5 and indicate whether all reasonably segregable portions of the requested records have been disclosed or provide ICAN with an unredacted copy of the requested records.

3. The Agency Improperly Withheld Records Under FOIA Exemption 6

a. Legal Standard

The Agency has not properly demonstrated that the withheld records fall under the scope of Exemption 6. *American Civil Liberties Union*, 628 F.3d at 619. Exemption 6 applies to prevent disclosure of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). When evaluating withholdings under Exemption 6, there is a "presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act." *Multi AG Media LLC v. U.S. Dep't of Agric.*,

515 F.3d 1224, 1227 (D.C. Cir. 2008) (quoting *Nat'l Ass'n of Homebuilders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002)) (internal quotation marks omitted). Therefore, an agency may withhold personal information only if "disclosure would compromise a substantial, as opposed to a de minimis, privacy interest." *Nat'l Ass'n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989).

Furthermore, even when a privacy interests exist, courts must "weigh the privacy interest in non-disclosure against the public interest in the release of the records in order to determine whether, on balance, the disclosure would work a clearly unwarranted invasion of privacy." *Lepelletier v. FDIC*, 164 F.3d 37, 46 (D.C. Cir. 1999) (internal quotation marks omitted); *see also U.S. Dep't of State v. Washington Post Co*., 456 U.S. 595, 598 (1982).

b. Application of Legal Standard

The Agency has failed to prove the applicability of Exemption 6 for two reasons. First, the Agency did not demonstrate the release of the withheld information would compromise a substantial privacy interest. *Nat'l Ass'n of Retired Fed. Emps*., 879 F.2d at 875. Instead, the Agency's Final Response asserted that "[The Agency] determined that the individual(s) to whom this information pertains has a substantial privacy interest in withholding it." (**Attachment 3**.) However, the information withheld by the Agency under Exemption 6 does not implicate a substantial privacy interest. The Agency employed Exemption 6 to withhold VAERS ID numbers throughout the production. For example, the Agency withheld the VAERS ID number in the subject line of the email on page 114 in Part 1 of the production; however, the same VAERS ID is left unredacted in the email directly below. It is unclear how the disclosure of this and the other VAERS ID numbers throughout the production implicates a substantial privacy interest. Without the presence of additional identifying information, a patient cannot be identified by a VAERS ID number. Therefore, this information does not appear to compromise a substantial privacy interest.

Second, the Agency did not properly weigh its asserted privacy interest against the public interest in the release of the records in order to determine whether, on balance, the disclosure would be a clearly unwarranted invasion of privacy. *Lepelletier v. FDIC*, 164 F.3d at 46. Although the Agency's Final Response asserted that there is a privacy interest in the withheld information; it made no mention as to whether that privacy interest was weighed against the public interest in disclosure. (**Attachment 3**.)

For these reasons, the Agency has failed to prove the applicability of Exemption 6. ICAN requests, the Agency prove the applicability of Exemption 6 or provide ICAN with an unredacted copy of the requested records.

4. The Agency Has Failed to Conduct an Adequate of Search

a. Legal Standard

The Agency has failed to conduct an adequate search for the requested records. An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. E.P.A.*, 767 F.2d 569, 571 (9th Cir. 1985) (quoting *Weisberg v. U.S. Dep't of Justice*,

745 F.2d 1476, 1485 (D.C. Cir. 1984)) (internal quotation marks omitted). "An agency fulfills its obligations under FOIA if it can demonstrate *beyond material doubt* that its search was 'reasonably calculated to uncover all relevant documents.'" *Defs. of Wildlife v. United States Border Patrol,* 623 F. Supp. 2d 83, 91 (D.D.C. 2009) (quoting *Valencia-Lucena v. U.S. Coast Guard,* 180 F.3d 321, 325 (D.C. Cir. 1999)) (citation omitted) (emphasis added). To satisfy its FOIA obligations, an agency needs to adequately describe the scope and methods of its searches, which can reasonably be expected to uncover the records sought and demonstrate that the places most likely to contain responsive materials were searched. *Davidson v. E.P.A.*, 121 F. Supp. 2d 38, 39 (D.D.C. 2000). At a minimum, the agency must specify "what records were searched, by whom, and through what process." *Steinberg v. U.S. Dep't of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994).

To determine whether a search for responsive records was adequate, a court must first determine the scope of the documents the plaintiff requested. *Wallick v. Agric. Mktg. Serv.*, 281 F. Supp. 3d 56, 66 (D.D.C. 2017). It has been long established that an agency has a duty to construe FOIA requests liberally. *See Hemenway v. Hughes*, 601 F. Supp. 1002, 1005 (D.D.C. 1985); *Conservation Force v. Ashe*, 979 F. Supp. 2d 90, 101-102 (D.D.C. 2013); *Rodriguez v. DOD*, 236 F. Supp. 3d 26, 36-38 (D.D.C. 2017). An agency has a duty under FOIA to select the interpretation that would likely yield the greatest number of responsive documents. *Conservation Force*, 979 F. Supp. 2d at 102-03; *Nat'l Sec. Counselors v. CIA*, 849 F. Supp. 2d 6, 12 (D.D.C. 2012). Technical precision is not required in FOIA requests, and a request certainly should not fail where the agency knew or should have known what the requester was seeking all along. *Inst. for Justice v. IRS*, 941 F.3d 567, 572 (D.C. Cir. 2019). A court can conclude a search is inadequate when the facts reveal a "positive indication of overlooked materials." *Valencia-Lucena*, 180 F.3d at 326.

b. Application of Legal Standard

The Agency's search was inadequate for two reasons. First, beyond indicating that a search was conducted, the Agency's Final Response did not adequately describe the scope and methods of its search. (**Attachment 3**.) Without specifying what records were searched, by whom, and through what process, ICAN cannot assume that the Agency's search was adequate. *Steinberg*, 23 F.3d at 552.

Second, the Agency did not properly interpret the scope of the FOIA Request. ICAN requested:

> **All communications** sent or received by Contracting Officer Representative Traci S. Roberts from August 27, 2020 through the date of the search concerning Contract 47QTCK18D0003 Task Order 75D30120F09621.

(**Attachment 1**.)

Traci Roberts ("**Ms. Roberts**") is listed as the Contracting Officer's Representative ("**COR**") on Task Order 75D30120F09621. (**Attachment 4** at 1). The task order requires GDIT to provide the Agency COR with a number of deliverables throughout the life cycle of the contract. (**Attachment 4** at 30-31.) Since Ms. Roberts is the Agency COR for this task order, the deliverables should have been provided to her; however, the production did not include emails to/from GDIT to/from Ms.

Roberts concerning the deliverables. The absence of these emails combined with the Agency's failure to adequately describe its search leaves substantial doubt whether the scope of ICAN's request was properly interpreted. *Conservation Force*, 979 F. Supp. 2d at 100-104.

For these reasons, the Agency has not demonstrated beyond a material doubt that its search was reasonably calculated to uncover all relevant documents. *Defs. of Wildlife*, 623 F. Supp. 2d at 91. Therefore, ICAN requests that the Agency conduct an adequate search and promptly produce the attachments contained within the production.

B. Appellate Request

Given the foregoing, ICAN hereby appeals and requests that the documents responsive to the FOIA Request be produced within 20 days of this appeal. Thank you for your time and attention to this matter. If you require any additional information, please contact us at **(212) 532-1091** or through email at **foia@sirillp.com.**

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.

Enclosures

Attachment 1

Siri | Glimstad

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CDC FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL December 8, 2022

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

Re: Contracting Officer Representative Communications Concerning Contract 47QTCK18D0003 Task Order 75D30120F09621 (IR#0971A)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

> **All communications sent or received by Contracting Officer Representative Traci S. Roberts from August 27, 2020 through the date of the search concerning Contract 47QTCK18D0003 Task Order 75D30120F09621.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and other medical treatments, and to provide the public with information to give informed consent. (**Attachment A**.) As part of its mission, ICAN actively investigates and disseminates scientifically based health information regarding the safety of vaccines and other medical treatments, for free through its website,[1] a weekly health news and talk show,[2] and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

[1] https://www.icandecide.org/.

[2] https://thehighwire.com/.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately take further administrative or legal action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin M. Farnsworth Esq.

Attachment A

DECLARATION OF CATHARINE LAYTON

STATE OF TEXAS

COUNTY OF Hays

I, Catharine Layton, being duly sworn on oath do say:

1. I am the Chief Operating Officer of the Informed Consent Action Network (ICAN), a not-for-profit 501(c)(3) organization whose mission is to disseminate scientific health information to the public.

2. I have been an officer of ICAN since its founding in 2016. I oversee all day-to-day operations of the organization and all ICAN's programs. Together with our CEO and Board, I ensure that all efforts are focused on our mission statement and ensure that ICAN stays in compliance with all required rules and regulations.

3. In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website hosts the organization's largest education program, The HighWire with Del Bigtree. Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

4. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

5. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts.

6. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act (FOIA).

7. ICAN uses records it obtains from its FOIA requests to carry out its public mission and support its role as a non-profit news-media organization in the field of health and medical safety, but as a non-profit, ICAN does not have a commercial interest in the records it seeks through FOIA.

8. Based on what I know as the Chief Operating Officer, as well what has been demonstrated by ICAN's past and current investigative reporting, for purposes of FOIA's Fee Waiver provisions, ICAN certainly qualifies as a "representative of the news media."

Signed 3 day of May 2022

Signature of Catharine Layton

I, Amy Blackwell Notary public for the state of Texas witnessed said Catharine Layton sign the above statement this 3 day of May (month), 2022

Notary Public for

AMY MARIE BLACKWELL
Notary ID #132597493
My Commission Expires
July 30, 2024

Attachment 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

December 13, 2022

Aaron Siri
Siri & Glimstad LLP
745 Fifth Ave., Suite 500
New York, NY 10151
Via email: foia@sirillp.com

Dear Mr. Siri:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated December 8, 2022. Your request assigned number is 23-00363-FOIA, and it has been placed in our complex processing queue.

Extension of Time

In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:

☐ We reasonably expect that records located would contain confidential commercial information. We are required to notify submitters of confidential information if their information is requested through a FOIA request. Submitters have 10 working days to object to the release of their information.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Anthony Clemons at qvr6@cdc.gov or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

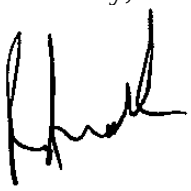
Fee Category

Because you are considered an “Other requester” you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact Anthony Clemons via email at qvr6@cdc.gov.

We reasonably anticipate that you should receive documents by April 12, 2023. Please know that this date roughly estimates how long it will take the Agency to close requests ahead of your request in the queue and complete work on your request. The actual date of completion might be before or after this estimated date.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

23-00363-FOIA

Attachment 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

August 7, 2023

Aaron Siri
Siri & Glimstad LLP
1005 Congress Avenue
Suite 925-C36
Austin, Texas 78701
Via email: foia@sirillp.com

Dear Mr. Siri:

This letter is regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of December 8, 2022, assigned #23-00363-FOIA, attached.

We located 957 pages of responsive records (702 pages released in full or part; 255 pages withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemptions 4, 5, & 6. The foreseeable harm standard was considered when applying these redactions.

EXEMPTION 4
Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. We have determined that the information withheld is customarily and actually kept private and confidential by the submitter of the information.

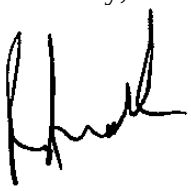
EXEMPTION 5
Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include internal emails.

EXEMPTION 6
Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as medical information. We have determined that the individual(s) to whom this information pertains has a substantial privacy interest in withholding it.

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by December 15, 2023.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

23-00363-FOIA

Attachment 4

ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 47

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER: 08/27/2020	2. CONTRACT NO. (If any): 47QTCK18D0003
3. ORDER NO.: 75D30120F09621	4. REQUISITION/REFERENCE NO.: 00HCVG1A-2020-49658

5. ISSUING OFFICE (Address correspondence to)
Centers for Disease Control and Prevention (CDC)
Office of Acquisition Services (OAS)
2900 Woodcock Blvd, MS TCU-4
Atlanta, GA 30341-4004

6. SHIP TO:
a. NAME OF CONSIGNEE: CDC DISTRIBUTION CENTER (Warehouse)
b. STREET ADDRESS: 3719 NORTH PEACHTREE RD.
c. CITY: CHAMBLEE | d. STATE: GA | e. ZIP CODE: 30341-2221
f. SHIP VIA:

7. TO:
a. NAME OF CONTRACTOR: GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.
DUNS NUMBER: 067641597
b. COMPANY NAME:
c. STREET ADDRESS: 3150 FAIRVIEW PARK DR STE 100
d. CITY: FALLS CHURCH | e. STATE: VA | f. ZIP CODE: 22042-4504

8. TYPE OF ORDER
☐ a. PURCHASE
REFERENCE YOUR: Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.
☒ b. DELIVERY
Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA: See Section B
10. REQUISITIONING OFFICE: HCVG1A

11. BUSINESS CLASSIFICATION (Check appropriate box(es))
☐ a. SMALL ☐ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED

12. F.O.B. POINT	14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
Destination		08/26/2022	Net 30 Days

13. PLACE OF: a. INSPECTION | b. ACCEPTANCE

17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	The Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) have a requirement for technical and programmatic support related to the Vaccine Adverse Event Reporting System (VAERS) SARS-CoV-2 vaccines. This task order will be placed on GSA Alliant 2. OFR/OAS: Lindsey Crockett,ywn1@cdc.gov, 770.488.2815 COR: Traci Sinetta Roberts, xct6@cdc.gov, 404.498.0669 CTR: (b)(6) (b)(6)					

18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT	20. INVOICE NO.		
			(b)(4)	17(h) TOT. (Cont. pages)

SEE BILLING INSTRUCTIONS ON REVERSE

21. MAIL INVOICE TO:
a. NAME: Centers for Disease Control and Prevention (FMO)
b. STREET ADDRESS (or P.O. Box): PO Box 15580 404-718-8100
c. CITY: Atlanta | d. STATE: GA | e. ZIP CODE: 303330080

(b)(4) — 17(i) GRAND TOTAL

22. UNITED STATES OF AMERICA (Signature): ▶Philip Denis -S
Digitally signed by Philip Denis -S
Date: 2020.08.26 16:24:28 -04'00'

23. NAME (Typed)
TITLE: CONTRACTING/ORDERING OFFICER

NSN 7540-01-152-8083
PREVIOUS EDITION NOT USABLE

OPTIONAL FORM 347 (REV. 6/95)
Prescribed by GSA/FAR 48 CFR 53.213(e)

SUPPLEMENTAL INVOICING INFORMATION

If desired, this order (or a copy thereof) may be used by the Contractor as the Contractor's invoice, instead of a separate invoice, provided the following statement, (signed and dated) is on (or attached to) the order: "Payment is requested in the amount of $_____. No other invoice will be submitted." However, if the Contractor wishes to submit an invoice, the following information must be provided: contract number (if any), order number, item number(s), description of supplies or service, sizes, quantities, unit prices, and extended totals. Prepaid shipping costs will be indicated as a separate item on the invoice. Where shipping costs exceed $10 (except for parcel post), the billing must be supported by a bill of lading or receipt. When several orders are invoiced to an ordering activity during the same billing period, consolidated periodic billings are encouraged.

RECEIVING REPORT

Quantity in the "Quantity Accepted" column on the face of this order has been ☐ inspected. ☐ accepted, ☐ received by me and conforms to contract. Items listed below have been rejected for the reasons indicated.

SHIPMENT NUMBER	PARTIAL FINAL		DATE RECEIVED	SIGNATURE OF AUTHORIZED U.S. GOV'T REP.	DATE
TOTAL CONTAINERS		GROSS WEIGHT	RECEIVED AT	TITLE	

REPORT OF REJECTIONS

ITEM NO.	SUPPLIES OR SERVICES	UNIT	QUANTITY REJECTED	REASON FOR REJECTION

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	VAERS SARS-CoV-2 The contractor shall provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs), and facilitate reporting to VAERS specifically pertaining to SARS-CoV-2. Reference the SOW and all associated deliverables. This is a T&M, severable line item. PoP: 08/27/2020 08/26/2022 Line(s) Of Accounting: 9390BSX 2512 2020 75-75-X-0512-0 2004111101 (b)(4) 9390FG5 2512 2020 75-2024-0943 C325111101 (b)(4)		(b)(4)	
0002	Travel/ODCs All travel must be in accordance with the Federal Travel Regulations (FTR). The Contractor shall obtain COR pre-approval of estimated travel expenses prior to travel occurrence. Charges will be submitted for actual costs incurred. The contractor shall ensure that the requested travel costs will not exceed the amount authorized in this task order. Other direct costs include travel and training requirements. All other direct costs must be pre-approved by the COR prior to occurrence. T&M, severable line item PoP: 08/27/2020 – 08/26/2022 Line(s) Of Accounting: 9390BSX 2512 2020 75-75-X-0512-0 2004111101 (b)(4) 9390FG5 2512 2020 75-2024-0943 C325111101 (b)(4)		(b)(4)	

0003	Contract Access Fee The Contract Access Fee (CAF) is 0.75% to be applied to the total price for contractor performance as billed to the government on each Task Order. The CAF is paid by the Ordering Agency, but remitted to GSA by the Contractor. Based on the established CAF rate, the Contractor shall include the CAF in each proposal. The Contractor shall include the CAF as a separate cost element per year on all quotes to the government, regardless of contract type. The CAF shall never be treated as a negotiable element between the Contractor and the Ordering Agency. The CAF Rate, effective at time of the Task Order award, shall remain the same for that Task Order for the full term of the Order. PoP: 08/27/2020 – 08/26/2022 Line(s) Of Accounting: 9390BSX 2512 2020 75-75-X-0512-0 2004111101 (b)(4) 9390FG5 2512 2020 75-2024-0943 C325111101 (b)(4)	(b)(4)

Task Order Total (b)(4)

STATEMENT OF WORK FOR
VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)
FOR SARS-COV-2 VACCINES

I. BACKGROUND:

The Vaccine Adverse Event Reporting System (VAERS) is a mandated program sponsored jointly by the Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA). The purpose of this project as authorized by the National Childhood Vaccine Injury Act (NCVIA), P.L. 99-660, is to provide a single nationwide mechanism to report, analyze and monitor vaccine adverse events (VAEs) that occur after receipt of vaccines. It also provides a vehicle for disseminating vaccine safety information to vaccines, family members, health care providers, vaccine manufacturers, government agencies, and other partners.

Vaccines represent one of the most cost-effective means of reducing or eliminating morbidity and mortality from selected infectious diseases. However, no vaccine is completely effective or safe. Recommendations for the use of vaccines are based on careful weighing of benefits of vaccination and risks of both the disease being vaccinated against and the immunization itself. Vaccines currently in routine use have been determined by various expert groups and FDA to have benefits that outweigh their risks. As part of any vaccination program, ongoing monitoring is essential to ensure that new or rare VAEs are recognized and appropriate measures taken. Vaccines undergo safety and efficacy testing in the laboratory and in controlled clinical studies before licensure or authorization (in the case of Emergency Use Authorization). Because these trials are limited in size, duration, and heterogeneity, rare, delayed, or unusual events caused by a vaccine may not be detected. Once a vaccine is used in the general population, post marketing surveillance is necessary to evaluate such VAEs.

To meet each agency's needs for vaccine safety monitoring data, CDC and FDA have jointly sponsored VAERS since 1990. The needs relate to CDC's public health responsibility for developing and issuing national vaccine policy recommendations and FDA's responsibility for licensing and regulating vaccines.

VAERS contains reports of VAEs based on two criteria, mandated and voluntary reports. The events mandated for healthcare provider and vaccine manufacturer reporting are listed in the Reportable Adverse Events Table (RET) available at https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf US-manufacturers of vaccines are mandated by 21 CFR Part 600.80 (Attachment 3) to submit reports routinely on a periodic basis, as well as in an expedited manner for more serious events. In addition, healthcare providers are encouraged to report all other clinically significant VAEs following the administration of any US vaccine in all age groups. For all reports, the impetus for reporting is not a presumed causal relationship between the vaccination and the event but may be based simply on the occurrence of the event temporally following vaccination and the lack of other obvious causes.

From 2014 through 2018, VAERS received an annual average of 53,000 reports, of which 45,500 were US reports. . Of the US reports, 5.0% were classified as serious (i.e., associated with disability, hospitalization, prolongation of existing hospitalization, life-threatening illness, congenital anomaly/birth defect, or death [21 CFR 600.80]). Since 1990, VAERS has received over 740,000 reports, most of which describe mild and self-limited adverse events such as injection site reactions and fever. (VAERS government data archive January 18, 2019.) VAERS helps to identify important new safety concerns and thereby can help inform vaccine policymakers and healthcare providers. In addition, the data are valuable for regulatory actions and vaccine research studies. The US Government considers post-licensure/authorization surveillance for any licensed and new vaccines through VAERS to be a nationally critical function, and the US Government considers the requirements of the VAERS activity to constitute essential services for which any lapse in coverage of services would be unacceptable.

The current COVID-19 pandemic and the anticipated COVID-19 vaccination program has created additional requirements for VAERS. Unanticipated project needs have materialized, requiring efforts beyond routine VAERS functions. Task requirements in support of public health emergencies (e.g., pandemic influenza, natural disasters and terrorist activities) and unanticipated federal mandates which are unpredictable necessitate an increase in Contractor staffing. These new requirements may result in increased workload for any of the tasks listed in the SOW Tasks 1-5. The Contractor shall be prepared to address unforeseen events/circumstances and meet the needs of the Government as it relates to such events. Reasonable accommodations will be made to the Contractor by the

Government to address unforeseen events/circumstances and the Contractor will be allowed to negotiate the implementation of changes.

II. OBJECTIVES:

The Vaccine Adverse Event Reporting System (VAERS) is the nation's frontline system for detecting potential vaccine safety concerns after vaccines are licensed or authorized for use in the United States. It is a nationwide mechanism by which VAEs may be reported, analyzed, and made available to the public. It provides a vehicle for disseminating vaccine safety information to vaccines, family members, health care providers, vaccine manufacturers, government agencies, and other partners. VAERS is a collaboration between CDC and FDA.

The purpose of this task order is to provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs) after administration of SARS-CoV-2 vaccines and facilitate reporting to VAERS. The objectives of the VAERS Project are divided into three categories: programmatic (mainly CDC), scientific (CDC and FDA), and regulatory (FDA).

Programmatic Project Objectives:

1. Create and maintain an online reporting website for VAEs following receipt of SARS-CoV-2 vaccines
2. Implement an electronic submission gateway for manufacturers to submit VAE reports on SARS-CoV-2 vaccines
3. Provide a reporting mechanism for VAEs that maintains submitted SARS-CoV-2 vaccines reports, including images of reports and medical documentation;
4. Ensure data in the VAERS reports are accessible to the public as required by law (P.L. 99-660, Section 2125), in accordance with policies to protect individuals' privacy;
5. Support CDC and FDA scientific staff in using VAERS data on VAEs after SARS-CoV-2 vaccines to rapidly respond to vaccine safety concerns or public health emergencies and in conducting epidemiologic and other scientific studies

Scientific Project objectives:

1. Rapidly detect new, unusual, or rare VAEs after SARS-CoV-2 vaccines;
2. Assess the safety of SARS-CoV-2 vaccines; or assess the safety in specific populations or situations where a new recommendation for SARS-CoV-2 vaccines occur;
3. Rapidly identify vaccine lots for SARS-CoV-2 vaccines with increased numbers or types of reported adverse events (FDA lead); and
4. Monitor trends in known VAEs after SARS-CoV-2 vaccines, particularly increases in reported VAEs

Regulatory Project Objectives:

1. Implement regulatory requirements related to VAERS, especially regarding reports from manufacturers after SARS-CoV-2 vaccines. [21 CFR 600.80].

III. SCOPE OF WORK:

The contractor shall provide support and technical assistance to CDC and FDA by supporting work in the following areas. The tasks below are not in order of priority. These tasks include:

1. Administrative
2. Report Receipt/Processing
3. VAERS Follow Up Activities and Enhanced Surveillance
4. Quality Control for VAERS Data
5. Information Management

Current VAERS plans, protocols, procedures, manuals, standard operating procedures (SOPs), software, some hardware, etc. may be provided by the Government for adoption/modification (i.e., the contractor would not have to develop all entirely new products, but would have the option of rolling over/adopting/modifying existing ones). Additionally, scanning reports for the image database, certain manual data entry tasks, and other processes clearly related to paper reports shall only apply to paper reports (i.e., electronic reports do not require scanning and manual data entry, but may require redaction).

IV. DESCRIPTION OF WORK:

The contractor shall implement a staffing and operations plan focusing only on vaccine adverse event (VAE) reports after SARS-CoV-2 vaccines. The total number of reports received during periods of peak activity (which are not expected to reflect sustained activity) is expected to be 1,000 reports per day, with up to 40% of the reports serious in nature.

TASK 1. ADMINISTRATIVE

STANDARDIZED METHODS FOR PROVIDING OPERATIONAL SUPPORT FOR THE VAERS PROGRAM.

A. The Contractor shall maintain Capability Maturity Model (CMM) Level 3 certification (or equivalent) or higher throughout the performance period of the contract and shall provide the Government current documentation of its CMM Level 3 (or equivalent) or higher certification.

B. The Contractor shall have staff available for program operations, systems maintenance and consultation during normal business hours (8:30 AM Eastern to 5:00 PM Pacific) to accommodate all four time zones within the continental United States. The rationale for this requirement is that it is essential for VAERS to be fully operational and for staff to be available to conduct systems maintenance and recovery during both east and west coast business hours and to also provide a reasonable level of service for the Hawaii-Aleutian time zone, since VAERS is a national spontaneous surveillance system.

C. The Contractor shall maintain a disaster recovery site for data management, data storage and all other VAERS data and IT functions that duplicates and replicates the primary production site and provides recovery of the production site within 24 hours (refer to **Task 5: INFORMATION MANAGEMENT** for capability requirements). This site shall be at least 100 miles away from the primary production site. The rationale for this requirement is that the disaster recovery site must be sufficiently distanced from the immediate area of the primary production site, but realistically within a business day's drive during an emergency.

D. The Contractor shall provide hardware, software, office and communications equipment and other resources to be used for data receipt, processing, editing, analysis, reporting, transmission, and storage. The Contractor shall ensure systems compatibility with CDC and FDA software and hardware requirements. The Contractor shall ensure that applicable technology is capable of upgrade or provide for replacement with later technology if necessary. Hardware, software and equipment shall be maintained and upgraded in accordance with industry standards for IT and telecommunications equipment including routine maintenance.

E. The Contractor shall upgrade VAERS program and related applications at the Government's direction through official modification signed by the Contracting Officer (CO), based on requirements gathered from Government and other program stakeholders, using structured, phased software development methodology.

F. The Contractor shall provide the Government with current and detailed system documentation. Documentation shall be maintained in two separate volumes: "Volume 1 – VAERS Business Processes" and "Volume 2 – VAERS IT Requirements and Design". Requirements shall be maintained in a formal requirements database, to be prioritized by a change control board consisting of CDC, FDA and Contractor personnel. Work will be prioritized using this process, in both a routine and expedited manner as appropriate. The Contractor must demonstrate adherence to formal CMM Level 3 methodology as the standard for project performance. System documentation will be presented in standardized text format,

generated in Microsoft Word document format (or other word processing format as specified by the Government), with all diagrams and other graphics contained as embedded objects with no external files or links, and presented in legible paper form or electronic form if requested by the Government. The Contractor shall provide detailed documentation of the technical procedures for data transport to the CDC and FDA, and documentation of technical details for source code and code relation, library dependencies, and data transport mechanisms. The Contractor shall provide the Government with this documentation within 30 days after contract award and annually or as requested thereafter, and new sections or documentation revisions will be provided to the Government upon implementation of changes in the system or procedures.

G. The contractor shall communicate with CDC and FDA, any requested changes to the system (including, but not limited to database structure, and data processes) prior to implementation. Modifications/changes will not be performed until approval from CDC and FDA.

H. The Contractor shall write standard operating procedures (SOPs) and modify them as needed. SOPs for all aspects of VAERS program operations, including complete VAERS report processing, shall be updated and provided to the Government annually or as requested. All SOPs shall be submitted to the Government for initial review and approval within 30 days after contract award and within 30 days of revision or implementation of changes, and minimally on an annual basis or as requested by the Government thereafter. SOPs shall be provided in a volume or series of volumes organized by subject, and will be presented in standardized text format, generated in Microsoft Word document format (or other word processing format as specified by the Government), with all diagrams and other graphics contained as embedded objects with no external files or links.

I. The Contractor shall provide VAERS operations and system orientation for Government employees as necessary (minimum once per year).

J. The Contractor shall produce and distribute the VAERS reporting form (Attachment A) and other forms as required for the operation of the VAERS program and reporting to VAERS. The VAERS program shall be identified as a Government program and the corporate name of the Contractor shall not be used on any form or correspondence to any entity other than CDC, FDA, or VICP, or used in any communication to represent the VAERS program unless approved by the Government.

K. The Contractor shall maintain lists of names, phone numbers, fax numbers, and E-mail addresses of contact personnel responsible for reporting from state health agencies, vaccine manufacturers, and immunization programs, limiting access and use to VAERS purposes only. The Contractor shall update this list on a quarterly basis and maintain this list for access by the Government in a manner specified by the Government.

L. The contractor shall shred all incoming documents once they are permanently saved electronically.

M. The Contractor shall establish, implement and maintain selected work groups as required by the Government throughout the life cycle of the contract, as needed and directed by the Government, and shall take and distribute minutes for working group meetings at the direction of the Government.

TRANSITION OF CONTRACT SERVICES

The Government considers VAERS an essential service; any lapse in coverage is considered unacceptable and can result in possible termination of contract. The Government requires a smooth and orderly transition of services.

A. No later than 60 days after the contract award the Contractor shall have established a system of operations as described elsewhere in this SOW and perform a functional evaluation of the system. Furthermore, the Contractor shall be able to receive VAERS reports after SARS-CoV-2 vaccines via any of the means specified in this contract (including electronically submitted reports from manufactures (eVAERS) and public (website). The Contractor shall also be able to perform all activities involving the handling and processing of reports submitted to VAERS including report receipt, processing, data entry, coding, quality

control, and report follow-up and verification. Contractor shall be able to provide data to the Government in the manners specified within this SOW, including the provision of data extracts, reports and report images, and meet this timeline development requirement as indicated for other activities and functions described within this SOW.

B. No later than 60 days after contract award the VAERS system maintained by the Contractor shall he fully operational and shall meet the satisfaction of the Government as to operational functionality.

C. No later than 60 days after contract award the Contractor shall meet all developmental and operational requirements in this SOW unless other specific timeline requirements for those requirements have been specified in the SOW.

D. No later than 60 days after contract award, the Contractor shall provide a Transition-Out Plan (end of performance period). The plan shall include a technical and management transition approach that is clear and complete and include a timeline and list of resources required for the transition. The Transition-Out Plan shall detail the planned transition methodology in logical sequence to ensure a smooth transition of all tasks and subtasks without interruption or decline in service quality. The plan shall also include a detailed description of risks (cost, technical, and performance) to both the Contractor and the Government, as well as risk mitigation strategies. Contractors shall also include all transition costs within their proposals. Please note that the continuity of services clause 52.237-3 is applicable and should be considered in developing the transition plan.

All documents and materials developed by the Contractor for the fulfillment of this contract, including all SOPs, manuals, security plans, management plans and plans of operations, and hardware shall be considered the property of the Government and may be disposed of by the Government in any manner at the Government's discretion.

CHANGES TO INFORMATION MANAGEMENT PROCEDURES AND TASKS

A. All tasks and activities specified in this SOW that pertain Information Management are subject to change, at the Government's discretinn, to accommodate and support fully electronic reporting to VAERS.

B. Reasonable accommodations will be made to the Contractor by the Government to allow for implementatiou of any such revised and updated Informatiou Management procedures and the Contractor will be allowed to negotiate implementation of changes within the scope via official modification.

UNFORESEEN EVENTS/CIRCUMSTANCES

Unanticipated project needs may materialize, requiring efforts beyond those described in this SOW. The Government may modify the contract to add task requirements (or enhance/expand current requirements) in support of public health emergencies (e.g. pandemic flu, natural disasters and terrorist activities) and unknown Federal mandates which are unpredictable and can initiate a workload surge, necessitating an increase in Contractor staffing. These new requirements may result in increased workload for any of the tasks listed in the SOW Tasks 1-5.

A. Approval Process for Unforeseen Events and Circumstances
CDC will provide the new work requirements and deliverables for each of the optional support services to the Contracting Officer (CO) as a revision to the SOW. The CO will send the contractor the revised SOW containing the new requirements. The contractor will review the requirements and provide a technical and cost proposal with the appropriate labor categories, number of hours, and labor rates to the CO. A contract modification (SF30) must be awarded by the CO to add any new optional support requirement. The contractor must not work outside of the SOW without authorization from the CO.

B. The Contractor shall be prepared to address unforeseen events/circumstances and meet the needs of the Government as it relates to any unforeseen events/circumstances. Reasonable accommodations will be made to the Contractor hy the Government to address unforeseen events/circumstances and the Contractor will be allowed to uegotiate the implementation of changes.

C. The implementation of activities to address unforeseen events/circumstances specified by the Government is dependent on the availability of core and supplemental funding to support such activities.

D. Examples of unforeseen events/circumstances that have impacted VAERS operations include (1) changes in the IT certification and accreditation process, (2) changes in regulatory requirements for reporting VAEs and transmitting data to CDC and FDA, (3) introduction of new vaccines resulting in necessary coding and database architecture changes, (4) changes in reporting requirements, report processing procedures, and data availability timelines to meet current public health needs, (5) urgently needed IT capability during public health emergencies or in preparation for anticipated public health emergencies, and (6) hardware and software upgrades to accommodate unforeseen events/circumstances. This is not an exhaustive list and other unforeseen events/circumstances may occur throughout the course of the contract performance period.

PROGRAM MANAGEMENT PLAN FOR CONTRACT ACTIVITIES

A. The Contractor shall develop and maintain a Program Management Plan (PMP). The Contractor shall prepare and maintain a phased Program Management Plan describing the tasks, milestones, risk management strategy, organizational resources, performance measures and management control to be employed to meet the cost, performance requirements and schedule of each phase of the VAERS project. The plan shall define the Contractor's governance process and include:

1. The management structure of the Program Management Team, organizational charts, key personnel and main points of contact, and identification of project teams and their roles and responsibilities.

2. Identification of all partners, sub-contracts, sub-contractor management, criteria for selection of sub-contractors, and description of services to be performed by sub-contractors. The Contractor shall not sub-contract out more than 25% of the work described in this SOW (i.e., 75% of the work requirements described in this SOW must be completed by the prime Contractor). Sub-contracting out clinical services tasks, report processing and data entry, coding, report follow-up activities, core IT activities, quality assurance, and core business and administrative tasks is strongly discouraged and will be viewed unfavorably and result in possible termination of contract.

3. Detailed mitigation response procedures in the event of unsatisfactory performance of program/project team members or sub-contractors.

4. Specification of strategies to include detailed timelines with critical milestones to ensure that both long-term, strategic goals as well as specific, targeted objectives are met efficiently and effectively.

5. The Contractor shall submit the PMP to the Government within 30 days after contract award and shall provide updates to the PMP annually or as requested by the Government. The PMP shall be in accordance with OMB Circular A-11, and the Federal IT Capital Programming Guide, Supplement to Part 7 of Circular No. A-11. Approval of the PMP by the Government shall be required.

B. Key Project Personnel: The Contractor shall employ and retain competent, qualified personnel to perform services of this contract in an effective, prompt, accurate, courteous and efficient manner. The Contractor shall provide a plan for staffing key positions for this project, providing detail about the criteria and selection process used to fulfill the requirements of this contract, and shall notify CDC in the event of changes in staffing of key positions. Staffing of these key positions shall be subject to Government approval. The Contractor shall provide all necessary supervisory, project management, managerial, clinical, technical and administrative support to meet the planning, implementation, operational and management requirements of this contract.

***NOTE FOR ALL TASKS*

Qualifications for personnel performing clinical activity (clinical staff) shall be subject to approval by the Government; the minimal education and experience qualifications for this activity shall be a nurse or other

clinical healthcare provider, with a minimum of 2 years of clinical or public health related experience. The manager of the follow-up activity shall be, at a minimum, an RN, PA, MD, DO or equivalent (e.g., MD from a foreign country who is not licensed to practice in the United States), The manager is required to have at least 2 years of clinical experience. The manager shall work closely with the Government to ensure that follow-up is conducted according to Government expectations.

REPORTING REQUIRMENTS:

A. PROGRAM MANAGEMENT MONTHLY STATUS REPORT - The contractor shall provide the Government with a monthly Program Management Monthly Status Report electronically to include the project's cost, progress, and issues in a format as directed by the Government. A copy of each monthly report shall be sent to the COR, the CO, and the FDA Technical Representative. The contractor shall document in the report the efforts performed in the completion of each project task. The report shall be due on the 15th day of each month following the month reported upon.

The Contractor shall propose format and data element recommendations for this report. The final format of the report shall be determined upon contract award.

B. ANNUAL REPORT - On an annual basis, the Contractor shall provide a written report to the Government documenting significant work activities and accomplishments for the preceding 12-month period. This report shall provide a historical record of major work activities accomplished, those ongoing and those not accomplished for the reporting period. As an appendix to the annual report, the Contractor shall deliver to the Government the current database dictionaries, standard operating procedures, and user manuals. The annual report shall be delivered to the Government no later than 30 days following the specified reporting period. One report shall be sent to the COR, the CO, and the FDA Technical Representative.

C. DRAFT FINAL REPORT - The Contractor shall provide a draft final contract report no later than 45 days prior to the expiration date of year 2 of this contract for review by the Government. The report shall include a written narrative highlighting major accomplishments under the contract. The report shall address each year of performance under the contract and document significant contractor findings, conclusions, recommendations, etc., to provide an objective review of contract activities. The Contractor shall provide copies of each draft final report electronically, and optional paper copies at the Government's request. One report shall be sent to the COR, the CO, and the FDA Technical Representative.

D. FINAL REPORT - Following review of the draft final report by the Government and receipt by the Contractor of the Government's written comments, the contractor shall provide a final report on or before the expiration date of the contract. The Contractor shall provide copies of each final report electronically, and optional paper copies at the Government's request. The report shall be sent to the COR, the CO, and the FDA Technical Representative.

FORMAT OF DELIVERABLES

Specific form format and additional content requirements of the delivery schedule items shall be coordinated between the Contractor and the Government, with a continued focus on providing useful and accurate reporting. The COR will provide the Contractor with disposal instructions for all technical documents (including, but not limited to all database dictionaries, databases, software, computer code, documentation, questionnaires, electronic files, etc.) in possession of the contractor at contract completion.

TASK 2. REPORT RECEIPT/PROCESSING

REPORTING TO THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) AFTER SARS-CoV-2 VACCINES

The Contractor shall perform the following tasks/activities:

A. Maintain communication protocols to provide assistance to the public for Vaccine Adverse Event Reporting System (VAERS) after SARS-CoV-2 vaccine-related questions. Communication protocols shall

involve appropriate telecommunication and electronic mechanisms for answering questions related to VAERS SARS-CoV-2 vaccine reporting and the VAERS system (e.g., how to obtain reporting forms, options for reporting, information referrals), and allowing for filing of VAERS reports over the phone in English or Spanish. The Contractor shall maintain communication protocols including, but not limited to: a toll-free telephone number and toll-free telefacsimile number to be listed as VAERS; a web site identified as VAERS, and an e-mail address (e-mail address may be specified by Government). The Contractor shall have staff available for consultation during normal business hours (8:30 AM to 5:00 PM) that accommodate all four time zones within the continental United States (refer to Task 1: ADMINISTRATIVE for options for active time zone coverage during normal business hours in the continental United States). The Contractor shall implement, maintain, and upgrade as necessary, telecommunication and electronic reporting systems to be available 24 hours-per-day (the toll-free telephone number is answered by machine after business hours). After-hours automated support shall be available 24 hours-per-day through the web and fax. See Emergency Preparedness section for after-hours support details. Contractor staff shall respond to messages received at the VAERS telephone number and messages sent to the VAERS e-mail address within one business day of receipt.

B. Staff the telephone system to provide telephone support for reporting during hours that accommodate normal business hours in the four time zones in the continental United States. The Contractor shall maintain a telephone voice message system, available at all times, which shall:

1. Provide a mechanism for callers to contact VAERS toll-free by telephone;

2. Provide coverage by automated menu choices for those times when Contractor staff does not immediately respond to calls to the telephone system;

3. Provide instructions to callers on ways to obtain the VAERS form and instructions on how to submit a VAERS report;

4. Provide directions to find the VAERS website and to submit a VAERS report using the internet-based reporting form;

5. Take messages at those times the telephone system is not actively staffed;

6. Provide information on the National Vaccine Injury Compensation Program (VICP) (website information: www.hrsa.gov/vaccinecompensation);

7. Provide additional information to callers as directed by the Government.

C. Maintain a United States Postal Service post office box identified as Vaccine Adverse Event Reporting System (VAERS) for SARS-CoV-2 vaccines and ensure, at a minimum, retrieval and logging of all mail from the post office box during each business day.

D. Maintain VAERS for SARS-CoV-2 vaccine electronic internet-based reporting system, utilizing appropriate system security precautions. This includes reports submitted by VAERS users such as state health coordinators, immunization programs, other Federal Government agencies and programs, and other parties. The procedures shall include methods for receipt of reports via the Internet and shall allow for reporters to submit an initial VAERS report for SARS-CoV-2 vaccines or a non-primary report using an Internet-based application, including an electronic version of the VAERS form for SARS-CoV-2 vaccines.

E. Maintain procedures to migrate data from VAERS SARS-CoV-2 vaccine manufacturer reports received electronically into the database, utilizing appropriate system security precautions. Manufacturer reports that must be received electronically include marketing expedited individual case safety reports (ICSRs), periodic ICSRs, as well as malfunction reports and 5-day reports required by the Combination product Post-market Safety Reporting Rule. Electronic manufacturer reporting using ICH E2B (R3) is referred to as eVAERS.

F. All methods for electronic transmission of reports developed and maintained for this project shall be based upon the HL7/ISO 27953-2 specification available at: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=53825, the ICH E2B(R3) Implementation Guide available at: http://www.ich.org/products/electronic-standards.html, the FDA E2B(R3) Implementation Technical Specification that will be available on CBER's ICSR website at: https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation , or other formats as specified by the Government.

G. Develop, document and implement procedures for the entry and processing of SARS-CoV-2 vaccine report data to ensure that the VAERS public data that is made available to the public is redacted of all protected health information (PHI) and other information that is protected under the Health Insurance Portability and Accountability Act (HIPAA) (http://www.hhs.gov/ocr/privacy/), or otherwise not publicly releasable for reasons of commercial confidentiality (as directed by the Government), regardless of the report source (paper/fax/other, web, e-report). Government users of VAERS SARS-CoV-2 vaccine data shall have access to personal identifiers from the specific fields for names, addresses, telephone numbers, etc. through the internet-based report viewing system created and maintained by the Contractor. Such data containing PHI shall be included at the direction of the Government in the Government Extract for the CDC, FDA or both.

H. Maintain a methodology to permanently archive electronically submitted VAERS SARS-CoV-2 vaccine reports as originally submitted, prior to any editing or redaction. The method shall allow for identification and retrieval of the reports from the archive database by specific report identifiers and by organization source of origin for reports submitted by manufacturers, state health coordinators, immunization programs, other Federal Government agencies and programs, and other parties.

I. Maintain methods to support a variety of Electronic Data Interchange (EDI) message types specified by the Government. The Contractor shall have the capability to both receive and transmit VAERS SARS-CoV-2 vaccine reports electronically in EDI formats specified by the Government and in additional electronic report submission formats consistent with electronic submission requirements based upon the HL7/ISO 27953-2 specification available at: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=53825, the ICH E2B(R3) Implementation Guide available at: http://www.ich.org/products/electronic-standards.html, the FDA E2B(R3) Implementation Technical Specification that will be available on CBER's ICSR website at: https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation, and other formats specified by the Government.

J. Under the direction and approval of the Government, the Contractor shall support additional EDI interface products for VAERS users. These include products from other vendors that use the VAERS web-reporting form, commercial off-the-shelf products, and other products as they are developed. An EDI interface product has been developed, utilizing the VAERS internet-based electronic submission form as a means for EDI electronic submission of VAEs by VAERS users from their immunizations databases. The Contractor shall successfully complete this task for existing, supported EDI interface products within 30 days after contract award. The contractor shall successfully complete this task for new EDI interface products of this nature within 30 days following direction from Government to perform this task.

STANDARDIZED METHODS FOR ENTERING AND PROCESSING VAERS SARS-CoV-2 VACCINE REPORTS

A. Report Data Entry and Processing Timeline Requirements:

The Contractor shall perform all necessary data entry for information submitted on VAERS forms for SARS-CoV-2 vaccine reports and related documents, and editing of the database, with all entry and edits tracked by date and entry staff and editors' individual identification. The Contractor shall be able to perform these activities within 30 days after contract award. See Appendix A (also in the section under Task 3) for information on scanning, data entry and coding timelines.

The timeline requirements for processing reports for VAEs of special interest to the Government (e.g., seizure) may differ from the above requirements and will be determined or otherwise agreed upon in SOPs approved by the Government. Timelines will be adjusted in response to changing public health needs, such as during a public health emergency or if a vaccine recommendation changes (e.g., a vaccine that was not previously recommended for children becomes recommended).

B. Documentation, SOPs, and user procedure manuals:

The Contractor shall perform the following tasks/activities related to adverse events reported after SARS-CoV-2 vaccines:

1. Maintain and update comprehensive documentation of database structure; design and analysis, including dictionaries, edits, report processing, and computer programs (including menu driven programs); user procedure manuals; and other tasks and functions and any modifications set forth in this SOW. Documentation shall adhere to the standards set forth elsewhere within this statement of work, to include Capability Maturity Model (CMM) standards.

2. Provide user-procedure manual(s) and SOP manuals for technical aspects of VAERS SARS-CoV-2 vaccine database operations to the Government within 30 days after contract award. Implementation of all procedures is contingent on Government review and approval.

3. Maintain, update and provide to the Government as requested complete documentation of the SARS-CoV-2 vaccines database and all regularly produced extracts. The documentation shall be readily available to the Government for use or reference and include data dictionaries for the datasets (including variable names, formats, descriptions, comprehensive list of legal codes) versions of the Medical Dictionary for Regulatory Activities (MedDRA) terms, (www.medramsso.com) or other coding language chosen by the Government, and look-up tables for vaccine, manufacturer, and MedDRA terms.

4. Maintain full, detailed documentation for all business and technical aspects of the VAERS SARS-CoV-2 vaccine program. Documentation shall be updated annually or as requested by the Government, and maintained in two separate volumes: "Volume 1 – VAERS Business Processes" and "Volume 2 VAERS IT Requirements and Design" as detailed in the Administrative section of this SOW.

5. Maintain a formal "requirements" database, to be prioritized by a "change request board" consisting of CDC, FDA and Contractor personnel. Work shall be prioritized by this process, in both a routine and expedited manner as appropriate to the requirement.

ACKNOWLEDGMENT, VERIFICATION, CODING AND DATA COLLECTION FOR ADVERSE EVENTS REPORTED AFTER SARS-CoV-2 VACCINES

The Contractor shall perform the following tasks/activities:

A. Review all documents received daily through all channels to prioritize processing, and assign a unique index number to each report received and initiate processing based on SOPS for the report category and method of transmission. The unique index number (VAERS ID number) shall appear in the personal data files and in files created for other information.

For electronically submitted reports and reports submitted using the internet-based reporting application, a unique index Electronic Report Number (ERN) shall be generated at the time the report is received, and shall be communicated back to the originator of the report using a formal acknowledgement or EDI submission confirmation message integrating the E-Report Number into the message. The ERN shall be included in the primary system database and in the Government extract, and in relational data tables providing linkage between the ERN and VAERS ID number assigned to each report and may be used to query the VAERS report in the master database and Government extract. For electronically submitted EDI

reports, sufficient information shall be retained from the EDI VAE message to uniquely identify the report and enable tracking and identification of the report within the primary system database.

B. Enter into the database all data submitted on report forms and related documents within the time limits specified in this SOW.

C. Code VAE data after SARS-CoV-2 vaccines on the VAERS report form (paper or electronic form/data), from related documents/records, and from additional information sources related to the report (i.e., records obtained during follow-up) using the most updated version of MedDRA (http://www.meddra.org/) or other coding source specified by the Government. Codes shall be entered into the database. Relational tables and data dictionaries shall be provided to the Government for all coding used throughout the system. The Government reserves the right to update and replace coding standards as required for the data elements, and reserves the right to introduce requirements for standardized coding for data elements not included in this SOW.

1. The Contractor shall enter into the database SARS-CoV-2 vaccine VAE descriptive clinical information and other symptoms, signs, lab data and/or disease entities, including text fields contained in Boxes 9, 10 11, 12, 18, and 19 on the VAERS reporting form (Available at https://vaers.hhs.gov/uploadFile/index.jsp) and code this information using MedDRA (or other coding language chosen by the Government). The specific boxes may change if the VAERS form is modified.

2. At the direction of the Government, the Contractor shall assess and potentially implement alternative methods for coding reports (computer assisted, automated, algorithm generated, etc.), and conduct post-implementation quality assurance. The implementation of alternative coding methods is dependent on the availability of core and supplemental funding to support such activities.

D. If requested by the Government, in the event that FDA approves new or modified labeling for a SARS-CoV-2 vaccine, the Contractor shall identify VAEs from the Adverse Reaction, Precautions, and Contraindications sections of the labeling and translate them into MedDRA (or other coding language chosen by the Government) terminology (known as labeled event data). When there is a change in labeling, the Contractor shall submit proposed modifications to the Government and modify the list of terms at the direction of the Government. All code lists or labeling changes submitted by the SARS-CoV-2 vaccine manufacturers must be approved by the Government before implementation.

E. At the direction of the Government, the Contractor shall develop, update, maintain, and provide data dictionaries for all data tables provided to the Government including the tables associated with vaccines, adverse event coding (MedDRA, or other coding language chosen by the Government), manufacturers, and labeled events associated w/vaccines. The labeled event dataset shall indicate labeled events associated with SARS-CoV-2 vaccines as identified in vaccine package inserts and product labels. The contractor shall enter labeled events within 10 working days following the introduction of a new vaccine or at the direction of the Government. The Contractor shall review and update the labeled events table annually or as necessary.

F. Comply with the safeguarding procedures for report forms as required by the NCVIA – 42 U.S.C. 300aa-25, and the safeguarding guidelines of the Privacy Act. The Contractor shall ensure that information which could identify an individual (such as name, street address, telephone number and email address of the person who received the vaccine and that person's legal representative) shall not be made available to any person other than the person who received the vaccine or the legal representative of such person and duly authorized staff of CDC, FDA and other participating federal entities. The restriction on access to identifying information applies to all information received by the VAERS activity, regardless of physical format (paper, electronic, other). The process shall be subject to review and approval by the Government.

G. Maintain storage of original and depersonalized data separately. Records shall be maintained in accordance with Privacy Act regulations and procedures and defined in the Automated Information Systems Security Program Handbook. Separate physical and electronic storage of original and redacted report data shall be maintained.

DATA AND DOCUMENT ACCESS, TRANSMISSION, STORAGE AND RETRIEVAL
(See Appendix A for detailed information on scanning, data entry and coding timelines).
The Contractor shall perform the following tasks/functions:

A. Maintain procedures to complete processing of death, 5-day, 15-day, serious, or other priority reports as specified in Appendix A, or upon request of the Government.

B. Make available to the Government an electronic copy of all received documents within the specified timeframes detailed in Appendix A. The Contractor system (currently a virtual private network [VPN] containing scanned images) enables Government staff electronic access to reports/documents while preserving the integrity of the original document.

C. Scanned reports and other documents that the Contractor makes available to the Government on the VPN do not require redaction unless specified by the Government.

D. Provide a data extract (Government Extract) of the VAERS SARS-CoV-2 vaccine data to the Government for storage and use at Government sites (both CDC and FDA) each business day, in accordance with this SOW.

E. Redact all PHI from reports to the VAERS database after SARS-CoV-2 vaccines that appear anywhere on the VAERS report form except boxes specifically asking for PHI. For example, if Box 18 on the VAERS 2.0 form states "I gave Mr. Jones his flu shot and then he had a reaction," the words "Mr. Jones" should be redacted from the VAERS database.

CHANGES TO REPORT RECIEPT AND PROCESSING

A. All tasks and activities specified in this SOW that pertain VAERS report receipt and processing are subject to change, at the Gnvernment's discretion.

B. Reasonable accommodations will be made to the Contractor by the Government to allow for implementation of any such revised and updated report receipt and processing procedures and the Contractor will be allowed to negotiate implementation of changes.

TASK 3: VAERS FOLLOW-UP ACTIVITIES AND ENHANCED SURVEILLANCE
The Contractor shall conduct follow-up on VAERS SARS-CoV-2 vaccine reports as specified by the Government in this SOW. Follow-up consists of the 3 parts outlined below:

- Communication Activities and Automated Record Collection
- Record Collection and Data Clarification
- Clinical Activities

COMMUNICATION ACTIVITIES AND AUTOMATED RECORD COLLECTION FOR VAERS SARS-CoV-2 VACCINE REPORTS
The Contractor shall:

A. Upon receipt of a death report from a family member, provide a condolence letter to express sympathy and explain VAERS procedures.

B. Provide immediate electronic acknowledgement to all persons who submitted VAERS reports via the Internet using the online reporting tool.

C. Provide acknowledgement in the form of a thank-you notification to all persons who submitted VAERS reports via paper format. Exceptions to this requirement are family members who report deaths, all manufacturers, and all state health coordinator reporters.

D. Develop and implement standardized letters, forms, logs, phone scripts and other documents, subject to approval by the Government, and implement documents developed by the Government at the direction of the Government, in order to verify the accuracy of submitted data.

E. Maintain procednres to request additional information from reporters or providers if information from essential items (2-6, 17, 18, and 21) on the initial VAERS report are missing, inconsistent or invalid. (See https://vaers.hhs.gov/pdf/vaers_form.pdf). Essential item nnmbers are subject to change if the VAERS form is altered or updated by the Government.

F. Maintain procednres to request disposition updates from reporters at 60 days and 1 year after report receipt for all serious reports with recovery status listed as not recovered. Include a request for any additional information. No 60-day update is required if routine follow-up has been conducted on the report.

RECORD COLLECTION AND DATA CLARIFICATION FOR SARS-CoV-2 VACCINE REPORTS

A. For all SARS-CoV-2 vaccine reports designated as serious by regulatory definition (death, life-threatening illness, hospitalization, prolongation of existing hospital stay, permanent disability, or congenital anomaly/birth defect), the Contractor shall attempt to collect follow-up records and additional documentation of the event (includes clarification of the event if necessary). In addition, for other adverse events of importance as determined by the Government, the Contractor shall attempt to collect follow-up records and additional documentation of the event. Follow-up activities include:

1. Identification and resolution of conflicting or incorrect information in the VAERS database and annotation in the VAERS graphic image file.

2. Retrieval of pertinent medical records including hospital discharge summary, labs, history and physical reports, medical, death certificates and/or autopsy reports. In addition, if the vaccination information is missing or nnclear (e.g., a report states "flu vaccine" but the brand or manufacturer name is missing) the vaccination record shall be obtained.

3. Scanning of all collected documents/records into the VAERS image base.

4. Other follow-up activities as directed by the Government.

Upon award of the contract, the Government will provide detailed, standard procedures for follow-up, which are subject to change based on the needs of the Government. See Appendix A for required timeframes for follow-up. VAERS correspondence can be via email or hardcopy letters.

Report Confirmation for SARS-CoV-2 Vaccine Reports

Confirmation correspondence is sent on receipt of a VAERS SARS-CoV-2 vaccine report submitted by a consumer or healthcare professional. Hardcopy letters or email correspondence are sent, depending on the person's communications preferences (specified in the VAERS report). Vaccine manufacturers do not receive these communications.

REPORT TYPE	FOLLOW-UP	CORRESPONDENCE TYPE
STANDARD - NO MISSING INFORMATION	Send letter or email	Confirmation*
STANDARD -INFORMATION MISSING	Send letter or email	Confirmation with request for missing information*
SERIOUS WITH "NO" FOR RECOVERY STATUS	Send letter or email	60 day follow-up and one year follow-up*
DEATH REPORTS FROM FAMILY MEMBERS	Send letter only	Condolence letter; consumers only*

**The Government will provide the format and wording of the letters for the contractor's use*

Medical Record Requests for SARS-CoV-2 Vaccine Reports
Requests for medical records are sent in follow-up* to a VAERS SARS-CoV-2 vaccine report.

REPORT TYPE	FOLLOW-UP	CORRESPONDENCE TYPE
SERIOUS-NON FLU VACCINE	Send request for medical records letter*	Request for medical records**
SERIOUS FLU VACCINE	Send request for medical records for flu vaccine reports letter*	Request for medical records for flu vaccine reports**
NON SERIOUS REPORTS OF SPECIAL INTEREST	Send request for medical records letter*	Request for medical records**
DEATH	Send request for death certificate letter	Request for death certificate**
FOREIGN	None	
MANUFACTURER REPORTS	None except death or if requested by the Government (of special interest).	
CLINICAL TRIALS	None	

**The Government will provide a guidance document to specify what records the contractor needs to obtain.*
***The Government will provide the format and wording of the letters for the contractor's use*

CLINICAL ACTIVITIES FOR SARS-CoV-2 VACCINE REPORTS

A. Clinical staff shall review follow-up records and add a narrative summary to the Government data for each report to reflect follow-up records collected. If records are not available, clinical staff may need to contact providers or patients to obtain follow-up information. For example, if a patient reports a serious adverse event but does not seek medical care, the patient or parent would need to be called to obtain the details and outcome of the event.

B. Clinical staff shall add appropriate MedDRA codes to the record to reflect data from the follow-up. An indicator variable will be provided to distinguish between initial and follow-up MedDRA codes, as well as, item number on the VAERS form.

C. Clinical staff shall edit or supplement as needed the relevant VAERS database record based on documents collected in follow-up (e.g., if the vaccine records differ from what is on the VAERS report, the vaccine information shall be corrected in the VAERS data).

D. Clinical staff shall complete Government-developed forms for specific reports which are intended to obtain supplemental information as directed by the Government.

E. Clinical staff are expected to pursue any leads that become apparent during the follow-up process and obtain information beyond what is detailed on any standard questionnaire that may contribute to an understanding of the underlying cause(s) of the adverse event in question. The information obtained from these leads shall be documented in narrative format by the follow-up staff. For example, if during follow-up the clinician learns that the patient had to be readmitted to the hospital, those records should be obtained and summarized in addition to the initial hospital admission records.

F. Information obtained during follow-up shall be clearly separated from information in the VAERS report when entering follow-up data into the VAERS database. The Government will provide instructions on how this will be accomplished. Follow-up information will NOT be included in the VAERS public data.

G. When unexpected, significant, or unusnal findings are identified dnring the performance of follow-up activities, findings shall be shared with FDA and CDC VAERS staff as determined by the professional judgment of the clinical staff.

H. Clinical staff shall stay current on vaccine recommendations and VAEs. A useful resource is the Advisory Committee on Immunization Practices website: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

I. Provide an indicator variable in the database that will specify if the medical records were collected and the type of records obtained.

TASK 4: QUALITY CONTROL FOR VAERS SARS-CoV-2 VACCINE DATA

The Contractor shall develop and implement a Quality Assurance Program (QAP). The QAP is applicable to all functional areas of this SOW and will allow the Government to verify that contract performance objectives are met, the best possible contract performance is being provided, and there is continuous improvement in the quality of contract services. The QAP is an important tool for using and monitoring performance indicators and ensuring the achievement of desired performance measure outcomes. The QAP shall establish quantitative evaluation strategies to ensure that contract performance measurements meet or exceed the highest levels of service.

The Contractor shall work with the Contracting Officer (CO) and Contracting Officer's Representative (COR) to develop standardized tools for assessing contract/project activities and provide consistent evaluation scoring. The Contractor shall conduct self-assessment and evaluation quarterly through the QAP and other strategies and methodologies to ensure quality performance of contract activities.

The QAP shall establish quantitative evaluation strategies to ensure compliance to the contract performance measurements and meet or exceed the highest levels of service. The plan should specify who within the Contractor's organization has oversight for quality initiatives. The Contractor shall provide this plan to the Government within 30 days after contract award. The plan should be updated as necessary (at a minimum annually) or as instructed by the Government to ensure that it remains current.

Quality control procedures shall be developed and implemented, subject to review and approval by the COR, for submitted data, entered data, scanned images, follow-up data and coded data. The areas to be addressed shall include completeness and accuracy of data, recovery status, follow-up, timelines of report processing for serious reports, unexpected occurrences (e.g., pandemic influenza, new recommendations), and completeness and accuracy of vaccine lot information on all VAERS SARS-CoV-2 vaccine reports.

QUALITY CONTROL AND ASSURANCE FOR ENTERED AND PROCESSED DATA FOR SARS-CoV-2 VACCINE REPORTS

A. The Contractor shall establish, implement, update and maintain standardized methods for confirming the quality of processed data through standardized quality control and quality assurance procedures designed to reduce or eliminate duplicate entries, data inconsistencies or deficiencies.

B. Subject to Government approval, the Contractor shall develop, demonstrate, document, and implement procedures to maintain data quality at a level adequate to support data analysis. The procedures shall include:

1. Automated editing procedures for data entered by the contractor using the Contractor's internal data entry system, including double-entry verification of entered data for select fields in reports as specified by this SOW.

2. Automated spelling checks for all text fields on the forms that undergo data entry by the contractor using the Contractor's internal data entry system. Automated spelling check functions shall include standard and custom dictionary spell check, including abbreviations and medical terminology. This process shall detect and alert the operator to possible spelling errors at the time of data entry, so that the operator can immediately implement appropriate corrections.

3. Incorporation of appropriate field restrictions, legal value checks, and background logic checks in the data entry software to ensure that the entered information is logical and appropriate before it is accepted. These procedures shall include, but will not be limited to, the following edit-checks listed below :

    a. Keystroke edit checks to ensure only correct values for the field are accepted. All other values cause the system to post an error/warning message.

    b. Within-field checks to ensure that data are valid for that field (e.g., entering numbers in a Name field is invalid and shall be flagged in error/warning). In addition, unusual values in fields, for example: 1) adverse event onset date before vaccination; 2) interval between vaccination date and onset date greater than 10 years, shall be flagged.

    c. Cross-field checks to ensure that information does not conflict with previously entered data (e.g., a death date is invalid if it is entered with a value prior to the date of birth or vaccination date/onset date prior to date of birth).

    All edit checks procedures shall have the ability to be modified as needed. The data entry system shall display warnings or error messages when unusual or incorrect information is entered for new records or for existing records which are retrieved and updated.

4. Automated spelling checks and edit-checks, as described above, used on the web data entry system and implemented in a manner that does not impede or significantly increase form completion time by users.

5. Development, implementation, utilization, documentation and reporting of internally calculated variables to define the quality of the data records entered. These variables shall be made available to the Government and shall be utilized in quality assurance programs and assessments by the Contractor and by the Government.

6. Establishment of an edit program that outputs missing and non-plausible data for visual verification with the corresponding VAERS form image record.

7. Establishment and implementation of a mechanism for correcting data errors detected in the previous steps.

8. Review of all data on a quarterly basis to examine frequencies of categorical fields and the distribution qualities of continuous variables for any non-plausible data, and verification of any non-plausible data indicated in this step.

    a. Establishment and implementation of a mechanism for data corrections indicated in the above review processes.

C. The Contractor shall perform double data entry on all US serious SARS-CoV-2 vaccine reports and other reports as specified by the Government. The verification process shall include data entry into two independent data files by different personnel unless otherwise approved by the Government. Report entries shall be matched by identification number and discrepancies shall be resolved. Target permissible data entry effort rates shall be subject to review and approval by the Government. If the Government identifies significant data entry quality concerns, then the requirement for double-data shall be increased to include all reports received until further notice from the Government.

D. All data entry procedures shall include real-time automated checks for illogical date relationships, invalid vaccine types, unavailable vaccines, invalid vaccine manufacturer combinations, invalid manufacturer or lot number, and other invalid data element combinations. Documentation of programming of these edit checks shall be submitted to the Government upon request. The data entry process shall be configured so initial data entry of records cannot be completed until all flagged data have been accepted as corrected or

moved to a queue for subsequent follow-up within one week. These later stages could include, at the discretion of the Government:

1. Addition of a module for acknowledgement letters sent to individual reporters to request clarification of missing or erroneous data; and

2. Referral of records to follow-up staff as described in the Follow-Up Section in this SOW for correction or completion of missing or erroneous data through follow-up activities.

E. The Contractor shall maintain and update a list of currently available SARS-Cov-2 vaccines during the contract period.

F. The Contractor shall maintain within the Relational Database Management System (RDBMS), a log of all manual edits of processed data, including deleted files, with date, editor, and nature of edit identified. All data contained in files deleted from the database shall be moved to a separate data set that shall remain available for review and retrieval.

G. Any errors identified by the Contractor QA checks or Government shall be corrected in the database.

QUALITY CONTROL AND ASSURANCE FOR SUBMITTED DATA QUALITY FOR SARS-CoV-2 VACCINE REPORTS

A. The Contractor shall develop, demonstrate, document, and implement mechanisms to detect and request missing or discrepant data from the reporter. The requests shall be made in the form of report acknowledgment letters or other methods at the direction of or with the approval of the Government and shall present incomplete data fields and discrepant data for review and completion or correction by the reporter.

B. The Contractor shall develop, demonstrate, document and implement mechanisms to detect, confirm, and link duplicate or redundant VAERS SARS-CoV-2 vaccine reports concerning the same adverse event. These mechanisms will be implemented as follows:

1. Initial data entry duplication search based on several key identifiers (e.g. name, date of birth, sex, vaccination date)

2. Two times per week (or as specified by the Government) data entry duplication search on key identifiers, and adverse event. An adverse event is defined as a single "person vaccination event" or the combination of a patient, reported vaccine(s), and adverse event(s), submitted by one or more reporters.

The following business rules and definitions shall apply to this activity:

a. The first SARS-CoV-2 vaccine report received by VAERS for a given adverse event shall be defined as the Primary Report. Other reports received after the Primary Report has been received and processed by the system shall be defined as Secondary Reports.

b. Any SARS-CoV-2 vaccine reports received by VAERS after the Primary Report has been received, which are exact duplicates (photocopies or identical printouts or identical web based reports) of the Primary Report, shall be defined as Exact Duplicate Reports. These Exact Duplicate Reports shall be destroyed upon recognition.

c. Any SARS-CoV-2 vaccine reports received by VAERS after the Primary Report has been received, which relate to the same "person vaccination event", but which are not exact duplicates of the Primary Report, shall be defined as Redundant Reports. Redundant reports may originate from different reporters reporting the same "person vaccination event", or may originate from the

same reporter as the Primary Report, or may provide different information about the adverse event, including information updates.

d. All SARS-CoV-2 vaccine reports that relate to the same "persnn vaccination event" shall be grouped together based on the VAERS ID for the Primary Report.

e. The manner of identifying the Primary SARS-CoV-2 vaccine Report and all subsequent (Secondary) reports shall he as follows, unless otherwise indicated by the Government. The Primary Report shall have the VAERS ID assigned at the time the report is entered into the system, followed by the identifier "-1". The first subsequent VAERS report concerning the same "person vaccination event" shall be assigned a "Linked Reponl" VAERS ID, which shall be the VAERS ID for the Primary Report, followed by the identifier "-2", at the time the report is identified as a redundant report. The second subsequent VAERS report concerning the same "person vaccination event" shall be assigned a VAERS ID, which shall be the VAERS ID for the Primary Report, followed by the identifier "-3", at the time the report is identified as a redundant report. Subsequent redundant reports shall continue to be numbered according to this pattern. The identifier digit following the hyphen shall be known as the "order number".

f. Assigning status regarding the serious nature (Item 21) on the VAERS form: death, life threatening illness, emergency room/department or urgent care visit, , hospitalization, prolongation of existing hospitalization, disability or permanent damage, congenital anomaly or birth defect, doctor or other health care professional office visit, none of the above) of the "person vaccination event" reported, as defined in 21 CFR 600.80, shall be based on the highest degree of severity for any of the reports received for a specific "person vaccination event". The report with the highest degree of severity shall take precedence in the determination of serious/non-serious status if discrepancies exist between the original report and subsequent reports. If there is uncertainty regarding a report's status as being serious or non-serious, reports should generally be adjudicated in favor of serious status.

C. As required, the Contractor shall develop, demonstrate, document, and implement a methodology by which data submitted by multiple reporters, in multiple documents from the same reporter, or obtained through follow-up or verification activities regarding the same event, are combined to create a composite table or tables which include the reconciliation of conflicting information through follow-up with the reporter, health care provider or parent/vaccine recipient. The Contractor shall amend the primary report with information from subsequent multiple reports on the same adverse event ("person vaccination event"), based on the accuracy of the information (e.g. medical records, follow-up information) or Government approval.

D. When a VAERS SARS-CoV-2 vaccine report is identified as being a Redundant Report or Duplicate Report and has been reassigned a VAERS report identification number based on the VAERS ID for the Primary Report with appropriate identifier tag (e.g., VAERS ID = 123456-2), the Contractor shall retain the VAERS ID number which has been replaced (referred to here as "Old VAERS ID") for the specific report in an accessible file for mapping to the current VAERS ID.

E. The Old VAERS ID shall be retained in a data table linked to the primary VAERS database to allow for the search and identification of any specific VAERS report by either the first VAERS ID assigned (the Primary Report ID until a report is identified as Duplicate or Redundant) or subsequently reassigned Linked Report ID.

F. The Contractor shall develop, demonstrate, document, and implement a coding variable (Patient Continuity Code) which shall be used to link a patient identified in a report to other reports in which that particular patient has been identified. Such reports may include Redundant and Duplicate Reports but may also include different "person vaccinatinn events" regarding the same person, but a different vaccination and/or event. The Patient Continuity Code shall be included in the primary system database and in the Government Extract.

G. The Contractor shall develop, demonstrate, document, and implement measures for batch-matching to identify redundant or secondary reports. The Contractor shall evaluate a variety of methods including "fuzzy logic"(http://en.wikipedia.org/wiki/Fuzzy_logic) for identifying possible duplicate or redundant reports, including reports linked with minor name variations, and implement them at the Government's discretion. An example of the use of fuzzy logic would be linking two different VAERS reports of a very rare occurrence in two patients who have the same birthdate and same date of vaccination but no name reported, into one VAERS report if the Contractor believes the two reports pertain to the same patient.

H. The Contractor shall develop and maintain methods for confirming the quality of submitted data through standardized quality control and quality assurance procedures designed to reduce or eliminate the presence of more than one record concerning the same adverse event, data inconsistencies or deficiencies.

I. With data provided by the Government, the Contractor shall develop and implement procedures to provide selection lists for valid vaccine lot identifiers (lot numbers) and data entry masks based on known lot numbers to provide information at the point of data entry as to the validity of the vaccine lot number entered. The Contractor shall develop and implement procedures to detect and specifically demarcate records containing reported vaccine lot identifiers, which are not valid lot numbers, based on comparison with lot identifier data provided by vaccine manufacturers through the FDA and provided to the contractor. These procedures shall be utilized for the Contractor internal data entry system.

J. Upon provision of SARS-CoV-2 vaccine manufacturers' lot numbers to the Contractor by the FDA, lot numbers in the database shall be flagged if not valid when compared to the manufacturer's master data.

K. Any errors identified by the Contractor QA checks or Government should be corrected in the data.

QUALITY CONTROL AND ASSURANCE FOR SCANNED DATA QUALITY FOR SARS-CoV-2 VACCINE REPORTS

A. The Contractor shall develop and maintain methods for assuring the quality of document images for the image database and correct indexing in the image database through standardized quality control and quality assurance procedures designed to confirm that documents are as legible as possible, complete, and capable of retrieval and copying from image base prior to final transfer of original physical document to the Government for archiving.

B. Any errors identified by the Contractor QA checks or Government should be corrected in the data.

QUALITY CONTROL AND ASSURANCE FOR CODED DATA QUALITY FOR SARS-CoV-2 VACCINE REPORTS

A. The Contractor shall develop and maintain methods for assuring quality and consistency and the most current version of coding in Medical Dictionary for Regulatory Activities (MedDRA) (or other coding language chosen by the Government) and the accuracy and completeness of MedDRA coding submitted by manufacturers in their reports. The Contractor shall notify the Government of changes made to the MedDRA codes relevant to the VAERS data coding activities and provide a full report and summary of each updated version of MedDRA.

B. The Contractor shall develop and implement a training program for all data entry and coding staff which shall require approval by the Government. The Contractor shall enforce a certification process that requires all coders to be trained and become certified coders for current code-based data. This shall include MedDRA, or another coding system chosen by the Government. The data system shall include a coder-signature field to indicate the specific coder staff person who performed the report coding.

C. The Contractor shall develop or procure and use automated tools, such as auto-coding software, algorithms and aides, when available and approved by the Government, to assist in the coding process.

D. The Contractor shall provide online manuals for coders to use at any time so that coders can access simulated scenarios and glean applicable codes.

E. The Contractor shall document any non-standard coding values in use by the VAERS program and submitted in reports.

F. The Contractor shall implement QA procedures and reviews to ensure that data provided as part of Government data extracts meet pre-specified requirements as directed by the Government. Procedures for data entry error identification, correction and supplemental data entry should be established by the contractor in advance of any error detection by the Government.

G. The Contractor shall develop and implement a QAP which shall include performance quality measures for each of the elements in this section of the SOW, and which shall require approval by the COR prior to implementation. The Contractor shall perform evaluation of these performance quality measures and report the results to the Government annually or on an alternate schedule as specified by the Government and propose procedure modifications as necessary to ensure data quality. The resultant modifications to QA procedures shall be periodically implemented contingent upon approval by the COR or CO.

H. Any errors identified by the Contractor QA checks or Government shall be corrected in the data.

QUALITY CONTROL UPDATES FOR SARS-CoV-2 VACCINE REPORTS

A. The Government reserves the right to direct the Contractor to revise and update QA procedures in the QAP to support changes in reporting procedures, such as changes to the VAERS form, online reporting tool, or standard methods of reporting (i.e., transitioning to fully electronic reporting).

B. Reasonable accommodations will be made to the Contractor by the Government to allow for implementation of any such revised and updated QA procedures and the Contractor will be allowed to negotiate implementation of changes.

TASK 5: INFORMATION MANAGEMENT FOR SARS-CoV-2 VACCINE REPORTS

A. VAERS is an integrated system that encompasses information technology, data management, data analysis, software development lifecycle and IT security. The Contractor shall perform the following tasks/activities:

1. Maintain Capability Maturity Model (CMM) Level 3 certification or higher throughout the performance period of the contract and provide the Government current documentation of its CMM Level 3 or higher certification.

2. Maintain current system operations

3. Provide software development, enhancement and progress reviews as requested by the Government.

4. Provide software documentation inclusive but not limited to systems requirements, specifications, architecture details, design details, analytical algorithms, data models, and technical support processes. All documentation shall be submitted to the Government in each annual report and during and following the implementation of system changes.

5. Provide data extractions and depersonalized data sets requested by the Government on a routine and ad-hoc basis

6. Provide ad hoc searches of VAERS SARS-CoV-2 vaccine data as requested by the Government

7. Implement appropriate Government policies and regulatory requirements regarding information management, information technology, software development, and security.

B. The Contractor shall furnish all necessary personnel, facilities, supplies, and equipment, as appropriate, to provide the Government with required technical, and operational services, within the general work parameters set forth in this Statement of Work.

VAERS SARS-CoV-2 SYSTEM SPECIFICATIONS

A. The VAERS system shall be hosted on an offsite network consisting of CDC owned software, commercial off the shelf software (COTS), and owned and leased hardware. The VAERS Servers will be categorized into core, non-core and infrastructnre systems. Core systems are those identified with core business functionality, non-core provides support for the core systems. The infrastructure servers will provide centralized security, network, authentication, storage, remote access and management of all the VAERS environments. These servers may consist of a combination of physical and virtual servers, though virtual servers are recommended.

The VAERS architecture should consist of two separate Security Sockets Layer (SSL) virtual private networks (VPN), one contains the production and software development lifecycle (SDL) environment, and the second located offsite contains a disaster recovery environment. The disaster recovery site is a duplicate and replication of the production site and provides recovery of the production site within 24 hours (refer to **Task 1: ADMINISTRATIVE** for physical location requirements for the offsite environment for disaster recovery, i.e., the disaster recovery site).

Below is an example of the approximate number of development, testing and user acceptance servers needed for the system:

Environment	Physical	Virtual
Infrastructure	7	5
Production	2	5
Disaster Recovery	6	12
Development	0	6
Testing	4	0
User Acceptance	0	5

B. Software to be installed on these machines includes but is not limited to:

Activator, ColdFnsion, Apache, Biscom FAXCOM, CentOS Enterprise Linux, Chado Software, SpellText, Cisco ASA software, Cisco IOS, CopSSH, Doubletake, Express Metrix, Faxcom, HP Array Configuration Utility, IBM Rational Tools, Itefix CopSSH, Java, Jpeg Wizard, Kofax Capture, Macromedia CFMX, Medical/Pharmaceutical Spellchecker, Microsoft Active Directory, Microsoft Remote Desktop Version 10, Microsoft Windows server 2016, Microsoft IIS, MS Office, MS OS, Microsoft SQL 2017, Microsoft VSS, NSClient++, PHINMS, Python, rDist, Redhat Enterprise Linux, rSync, RSA Authentication Manager, RSA Radius Server, SAS, Screen, SourceForge GNUWin32, SpellText, Stedman's spellchecker, Superflexible, Symamtec Backup Exec Agent, Symantic Antivirus, Tripwire for Servers, VMWARE, Zope

Contractor must license or own software (or equivalent) as listed above.

C. Contractor must develop a VAERS Virtual Private Networks (VPN) which allows authorized users located outside of the Contractor's facility to establish a secure connection to the VAERS application. The VAERS VPNs will provide a secure computer network that uses the Internet to allow remote users secure access to the VAERS application and database. It should encapsulate data transfers each business day, between the authorized users and Contractor's networked devices to keep transferred data private from other devices on one or more intervening local or wide area networks. Depending on the user's access rights to the VAERS database, the individual will either be part of a VPN with full access to the VAERS database or a more restricted VPN only providing access to reports of selected research interest. The Contractor adheres to the following and is expected to create and maintain capabilities to perform these functions:

- Conduct web based query
- Enable viewing of scanned images
- Enable viewing of entered data including Follow up and MedDRA code
- Enable viewing of nurse follow up module

D. Other VAERS functionality requirements include:

1. Creation of a VAERS SARS-CoV-2 vaccine public website and online reporting tool which includes a mechanism for allowing patients, parents, providers and other partners and stakeholders to electronically submit VAERS reports

2. Creation of an intranet application that allows authorized staff to access SARS-CoV-2 vaccine reports to query, add and modify data, and view linked images

3. Double data entry of specific report types as determined by the Government

4. Scanning of hard copy documents including, but not limited to, VAERS SARS-CoV-2 vaccine report and medical documentation.

5. Receipt of electronic SARS-CoV-2 vaccine reports from manufacturers (eVAERS)

6. Electronic transmission of reports and data extractions to CDC and FDA as specified by the Government

7. Business Intelligence

8. Data warehousing

9. Data editing

10. Duplicate identification

11. Database management system and tools

12. Software for extracting and transmission of Government specified data sets.

DATA MANAGEMENT

A. All Information Technology (IT) systems must comply with federal regulations and policies regarding IT which includes but are not limited to Enterprise Performance Life Cycle (EPLC), Capital Planning and Investment Control (CPIC), Information Security, Section 508 of the Rehabilitation Act, Enterprise Architecture (EA), etc.

B. These methods, procedures and processes will accept reports submitted by business partners including manufacturers, state health coordinators, and other immunization programs, other Federal Government agencies and programs, and other parties.
Electronic manufacturer reports include post-marketing adverse drug reaction (ADR) data for individual cases, post-marketing expedited ADR reports and periodic ADR reports. Electronic manufacturer reports shall conform to the format and processes identified and implemented by the US Food and Drug Administration (FDA). This reporting process is referred to as eVAERS.

C. Under the direction of the CO and COR, the Contractor shall establish and maintain methods, procedures and processes to support a variety of Electronic Data Interchange (EDI) message types to be specified by the Government. The contractor will work with SARS-CoV-2 vaccine manufacturers (approved by Government), to ensure electronic submission of postmarket individual case safety reports (ICSRs) to VAERS using E2B(R3) and submitting via xml format. Electronic reporting of vaccine postmarketing

safety reports shall follow the International Council on Harmonisation's (ICH) E2B(R3) ICSR specification : https://www.federalregister.gov/documents/2014/06/10/2014-13480/postmarketing-safety-reports-for-human-drug-and-biological-products-electronic-submission

STANDARDIZED METHODS FOR PROVIDING ROUTINE AND REQUESTED REPORTS OF VAERS SARS-CoV-2 VACCINE DATA TO THE GOVERNMENT

A. The Contractor shall perform ad hoc searches of the VAERS SARS-C0V-2 vaccines databases to address specific surveillance questions and support vaccine safety studies, as requested by the Government.

B. At the direction of the Government the Contractor shall develop, maintain and update programs to routinely produce specific depersonalized data sets containing originally reported information for the public websites, World Health Organization (WHO), state health coordinators and others as approved by the Government.

C. The Contractor shall provide a weekly reports of adverse events after SARS-CoV-2 vaccines reported for specific jurisdictions via The Epidemic Information Exchange (Epi-X) to those specific State Health Coordinators as indicated by the Government, upon request by the Government.

These reporting requirements are subject to change at the request of the government.

GOVERNMENT DATA EXTRACTS FOR SARS-CoV-2 VACCINE REPORTS

A. The quality of the data extract is important to VAERS, therefore, the Contractor shall provide accurate data extract ("Government Extract") to the Government for storage and use at Government sites (both CDC and FDA). The data extract and all available data elements collected from the submission of VAERS reports and collected through follow-up activities are subject to the approval of the Government and should be provided according to the specified timeframes detailed in Appendix A. The complete VAERS SARS-Cov-2 vaccine database, containing both (a) all data elements from the VAERS form which include those data-elements historically used by the Government, and (b) any new and valuable data-elements added by the Contractor by the direction of the Government shall be provided daily. All data elements collected on the VAERS form (and subsequent approved revisions of the VAERS form), and subsequent data elements collected via internal entry system or web system, are subject for inclusion in the data extract to Government. If the data element is a specific field on the form, the data shall be stored in a related specific field in the Government data, with no concatenation of data fields or elements. The following are examples of two processes for important extracts of data from the VAERS system that the Contractor shall follow:

1. VAERS SARS-CoV-2 VACCINE DAILY EXTRACT - Each business day, the Contractor shall send an extract to the CDC and FDA through a low cost data transmission application. Once CDC receives the extract, a confirmatory e-mail is submitted to the Contractor verifying that the extract has been received. The Contractor shall contact the COR if the confirmatory e-mail is not received. The COR will contact the Contractor if there is a problem uploading and processing the data. The Contractor shall adhere to the following:

    - Include initial report data and data obtained in follow up
    - Provide data in a format approved by the Government (CSV format)
    - Maintain manufacturer reports received electronically including postmarketing adverse drug reaction (ADR) data for individual cases, post marketing expedited ADR reports and periodic ADR reports.

2. VAERS SARS-CoV-2 VACCINE PUBLIC EXTRACTS - The Contractor shall be required to maintain public redacted databases of VAERS data as specified by the Government. The current VAERS public website (www.vaers.hhs.gov) provides downloadable datasets that are subsets of the VAERS daily extract that is sent to the CDC and FDA. WONDER, a CDC created online tool located at wonder.cdc.gov, is another example of the public databases. This tool allows the public to query a subset of the VAERS data. Standard operating procedures are used to ensure patient privacy. The

public website and WONDER shall be updated on a weekly basis. There is a one week lag on data so that quality control measures can be conducted by the Contractor. The datasets on the public website are split into separate CSV files by years dating from 1990 to the current year. Non-domestic (i.e., foreign) reports are placed in a separate CSV file.

3. VAERS SARS-CoV-2 VACCINE OTHER GOVERNMENTAL AGENCIES EXTRACTS- The Contractor shall provide VAERS data in comma separated value (CSV) files on a secure server platform to specified points of contact among other governmental agencies, Department of Defense (DoD), Indian Health Services (IHS), and World Health Organization (WHO), on a weekly basis.
   a. DoD and non-DoD reports will be identified using specific search criteria as outlined in VAERS CDC DoD Memorandum of Agreement (MOA). Initial and follow-up unredacted information will be provided on DoD reports, while initial redacted information will be provided on non-DoD reports.
   b. IHS and non-IHS reports will be identified using specific search criteria as outlined in VAERS CDC IHS Memorandum of Understanding (MOU). Initial and follow-up unredacted information will be provided on IHS reports, while initial redacted information will be provided on non-IHS reports.
   c. WHO will be provided initial redacted information, similar to data publicly available at the CDC WONDER website: https://wonder.cdc.gov/vaers.html.

4. VAERS SARS-CoV-2 VACCINE JURISDICITON EXTRACTS- The Contactor shall provide VAERS SARS-CoV-2 vaccine data and summary tables to specified jurisdictions using CDC's Epidemic Information Exchange (*Epi-X*), a secure, web-based network that serves as a powerful information exchange between CDC and public health professionals involved in identifying, investigating, and responding to public health threats. Data will be posted and refreshed on a weekly basis with a one week lag in order to incorporate quality control measures conducted by the Contractor. The VAERS SARS-CoV-2 vaccine data will include initial report data with personal identifiers, no follow-up will be included. Summary tables will also be provided to the jurisdictions, including summary statistics, including but not limited to, serious status and conditions of interest.

VAERS FUTURE SOFTWARE DEVELOPMENT AND ENHANCEMENTS

A. At the request of the Government, the Contractor shall develop and enhance software for the VAERS system following the HHS, CDC and NCEZID policies and procedures for Enterprise Performance Life Cycle (EPLC), Capital Planning and Investment Control (CPIC) and IT security. http://www.hhs.gov/ocio/policy/index.html

CONTRACTOR COMPLIANCE WITH APPLICABLE LAWS, REGULATIONS, POLICIES AND STANDARDS

A. The Contractor shall ensure that the Information Technology Architecture (ITA) for the VAERS system is implemented and maintained by the Contractor in compliance with applicable regulations including OMB Circular A-130, the Federal Information Resources Management Regulation (FIRMR), the DHHS Automated Information Systems Security Program (AISSP) Handbook, and applicable portions of the CDC ITA plan, Technical Reference Model and Standards.

B. IT products and technologies procured through this contract shall meet the applicable accessibility standards at 36 CFR 1194, viewable at https://www.gpo.gov/fdsys/granule/CFR-2011-title36-vol3/CFR-2011-title36-vol3-part1194/content-detail.html

C. The Contractor shall ensure that all systems are in compliance with Section 208, the privacy provisions of the E-Government Act of 2002, and follow the OMB Guidance of September 26, 2003 regarding implementation of the privacy provisions of the E-Government Act.

D. The Contractor shall be responsible for being aware of and shall comply with all applicable federal information technology and information management laws, regulations, policies, and standards. These include but are not limited to:

- Children's Online Privacy Protection Act (COPPA)
- Section 508 of the Rehabilitation Act. HHS Section 508 Prodnct Assessment Template (nse VPAT version 2.0 or later: https://www.itic.org/policy/accessibility/vpat)
- Clinger-Cohen Act (CCA
- Federal Information Security and Management Act (FISMA)
- Paperwork Reduction Act (PRA
- Office of Management and Budget (OMB), National Institute of Standards and Technology (NIST), and General Accounting Office (GAO) policies that can be primarily found at or through the Federal CIO Council website at www.cio.gov.
- Federal Enterprise Architecture (FEA)

E. The Contractor shall not develop any Internet web applications that use persistent cookies without explicit authorization by CDC's Chief Information Officer.

F. The Contractor shall adhere to CDC's Secure Coding Practices gnide for developing web-based applications to prevent security vulnerabilities.

G. Contractor's performance and resulting deliverables shall adhere to all federal, HHS, and/or CDC IT security policies and procednres. Development or implementation of an electronic information system or any electronic data collection effort conducted in the performance of this contract is required to undergo Certification and Accreditation (C&A) prior to operation. When applicable, the Contractor shall be required to complete all security documentation and materials required to obtain an authority to operate (ATO). The Contractor shall comply with all applicable HHS, CDC, FISMA, HIPPA, NIST, and other federal policies and regulations in the performance of the security requirements. If an application or system is operated by the Contractor on behalf of the Government and/or hosted at a Contractor facility, it shall comply with HHS and CDC policies, and is subject to all OMB requirements, including a full Certification and Accreditation (C&A)

V. TASK ORDER DELIVERABLES AND MILESTONES:

Item	Deliverable	Quantity	Time
1.	Program Management Monthly Status Report as specified in the Administrative section of the SOW	1 each to the COR and TR	Monthly, first report due 30 days after contract award
2.	Annual report as specified in the Administrative section of the SOW	1 each to the COR, TR and CO	Annually, due 30 days following the 12 months period covered by report
3.	Draft Final Report as specified in the Administrative section of the SOW.	1 each to the COR and TR	At least 45 days before the contract completion date
4.	Final Report as specified in the Administrative section of the SOW	1 each to the COR, TR and CO	No later than the contract completion date
5.	Report inventory of all hardware and software, including version numbers of software and record of maintenance as specified in Security section of the SOW	1 each to the COR and TR	Include in annual report and upon request
6.	Develop/update and provide standard operating procedures for all aspects of VAERS operations, including complete VAERS report processing, as specified in the Administrative section of the	1 each to the COR and TR	Within 30 days after contract award, within 30 days of implementation of changes, and then annually and upon request

Item	Deliverable	Quantity	Time
	SOW		
7.	Develop and maintain list of names, phone nnmbers, fax numbers, and email addresses of contact personnel responsible for reporting from state health agencies, vaccine manufacturers, and immunization programs as specified in Administrative section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually, and upon Government request.
8.	Report number, method of contact, type of contact with VAERS by manufacturers, state health coordinators, immunization programs, and the public.	1 each to the COR and TR	Include in the annual report, and upon Government request
9.	Provide documentation of the technical procedure for data transport to Government as specified in the Information Management section of the SOW.	1 each to the COR and TR	Within 30 days after contract award
10.	Provide Government Extract of VAERS data to both agencies as specified in the Information Management section of the SOW.	1 each to FDA and CDC designees	Beginning 30 days after contract award, and each business day thereafter
11.	Maintain and provide documentation for a current, separate mirror version of the VAERS system and RDBMS as specified in SOW.	1 Each to the COR and TR	Within 90 days after contract award
12.	Provide user-procedure manual(s) and standard operating procedures (manual of operations) for technical aspects of VAERS database operations	1 each to the COR and TR	30 days after contract award and then as specified in SOW
13.	Provide documentation for data verification procedures including standardized letters, forms, logs, phone scripts and other documents as specified in SOW	1 each to the COR and TR	Upon Government request
14.	Provide a weekly report of adverse events after SARS-CoV-2 vaccines to Vaccine Safety Coordinators and their designees of specific jurisdictions as indicated by the Government as specified in SOW	1 each to the COR and TR	Weekly, beginning 60 days after contract award
15.	Provide documentation for procedures and rules for Data Quality Control and Assurance as specified in SOW	1 each to the COR and TR	Provide 60 days after contract award then annually or upon request
16.	Provide System Security Plan and training materials for employee AIS security training program as specified in the Information Management section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually
17.	Provide Program Management Plan as specified in the Administrative section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually or upon request
18.	Provide Quality Assurance Program (QAP) plan as specified in SOW	1 each to the COR, TR and CO	Within 30 days after contract award, then annually
19.	Provide list of key project personnel as specified in SOW	1 each to the COR, TR and	Within 30 days after contract award, then annually; update within 10 days

Item	Deliverable	Quantity	Time
		CO	following key personnel changes
20.	Provide Earned Value Report as specified in Information Management and Administrative sections of SOW	1 each to the COR and TR	Include in monthly reports
21.	Provide Data System Security Plan or information system security plan (SSP) as specified in Information Management section of SOW	1 each to the CO and COR	Draft within 30 days after contract award; final version within 60 days after award.
22.	Provide list of staff who have successfully completed information security training as specified in Information Management section of SOW	1 to COR	Upon request by COR
23.	Provide documentation of Level 3 Security Requirements compliance as specified in the Information Management section of SOW.	1 each to COR and TR	Within 30 days after contract award
24.	Provide Transition-Out Plan for approval as specified in the Administrative section of SOW	1 each to the COR and TR	Within 60 days after contract award
25.	Provide Disaster Recovery Plan for approval as specified in the Information Management section of SOW	1 each to the COR and TR	Within 60 days after contract award
26.	Provide results of IT Security Risk Management Assessment as specified in the Information Management section of SOW	1 each to the COR and TR	Within 45 days of completed assessment
27.	Provide the Government with detailed system documentation. Documentation shall be maintained in two separate volumes: "Volume 1 – VAERS Business Processes" and "Volume 2 – VAERS IT Requirements and Design" as specified in the Administrative section of SOW	1 each to the COR and TR	Within 30 days after contract award, then annually thereafter, with new sections or documentation revisions provided within 10 days
28.	Provide detailed documentation of the technical procedures for data transport to CDC and FDA as specified in the Administrative section of SOW	1 each to the COR and TR	Within 30 days after contract award, then annually thereafter, with new sections or documentation revisions provided within 10 days

The Contractor shall provide, upon request from the Government, deliverables not specifically listed in this document. The Government will provide the Contractor with sufficient time (i.e., a minimum of 2 business days) to fulfill such requests.

VI. PERFORMANCE MATRIX:

Desired Outcomes	Required Services	SLA Performance Standard (completeness, cost, reliability, accuracy, timeliness, quality)	Acceptable Quality Level (AQL)	Monitoring Method (Quality Assurance Surveillance Plan/QASP)	Incentives/ Disincentives

Desired Outcomes	**Required Services**	**SLA Performance Standard** (completeness, cost, reliability, accuracy, timeliness, quality)	**Acceptable Quality Level (AQL)**	**Monitoring Method (Quality Assurance Surveillance Plan/QASP)**	**Incentives/ Disincentives**
Execute/perform all required tasks according to performance plan	Meets and complies with defined task requirements	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified in this Statement of Work	100% compliance	COR oversight	Favorable or Unfavorable Performance Evaluation
Send timely VAERS Daily Extracts with correct information	Each business day the Contractor sends an extract to the CDC and FDA through the PHINMS or other specified application.	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified in this Statement of Work	98% compliance	Daily receipt of Extract	Favorable or Unfavorable Performance Evaluation
Process all serious reports within the specified timeframe reflected in Appendix A of this SOW.	Process serious reports in the established timeframe to electronically migrate VAE data into the database.	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified in this Statement of Work	100% compliance All late logging of adverse events reports is reported in monthly report.	Monthly Quality Reports	Favorable or Unfavorable Performance Evaluation

VII. PERIOD OF PERFORMANCE:

Base: 27 August 2020 – 26 August 2021
Option: 27 August 2021 – 26 August 2022

VIII. PLACE OF PERFORMANCE:
The work will be conducted at the contractor's facility.

IX. EQUIPMENT AND INFORMATION:
The Contractor shall provide hardware, software, office and communications equipment and other resources to be used for data receipt, processing, editing, analysis, reporting, transmission, and storage. The Contractor shall provide the Government with current and detailed system documentation, including SOPs for all aspects of VAERS program operations, including complete VAERS report processing, submitted to the Government for initial review and approval within 30 days after contract award and within 30 days of revision or implementation of changes, and

minimally on an annual basis or as requested by the Government thereafter. Please see Task Order 1 (Administrative) for more detail.

Appendix A: VAERS triaging of reports in business days[1, 2]

Category	Serious reports		Serious follow-up initiation	Non-serious reports	
	Scan within	Complete process within[3]		Scan within	Complete process within[3]
1. US Deaths[4]	1	1	1	N/A	N/A
2. US 5-day reports	2	2	N/A	N/A	N/A
3. US 15-day reports	2	2	N/A	N/A	N/A
4. US reports[5]	2	3	3	2	5
5. US 30-day reports	2	20	N/A	2	20
6. Foreign reports	5	90	N/A	5	120

1.Subject to change in response to new public health policies and/or events and/or funding availability after discussion between CDC and FDA
2. Not applicable for GBS reports where a patient is confined to facility longer than the time allowed for follow-up (e.g., patient in rehabilitation after GBS)
3. Completion includes scanning, data entry, and coding
4. If final autopsy report is not received within 2 months, make request every 2 months
5. If no records received within 5 days from the original request, make another request for Covid-19

CLAUSES

In addition to the GSA schedule contract clauses, the following clauses are incorporated:

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (AUG 2019)

(a) Definitions. As used in this clause—
Covered foreign country means The People's Republic of China.
Covered telecommunications equipment or services means-

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means-

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;
(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled

i (i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

i (ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) Prohibition. Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in Federal Acquisition Regulation 4.2104.

(c) Exceptions. This clause does not prohibit contractors from providing

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement.

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at https://dibnet.dod.mil.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause:

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (e), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance

hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days.

(End of Clause)

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided, that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 60 months.

(End of Clause)

CDC 42.0002 Evaluation of Contractor Performance Utilizing CPARS (April 2013)
In accordance with FAR 42.15, the Centers for Disease Control and Prevention (CDC) will review and evaluate contract performance. FAR 42.1502 and 42.1503 requires agencies to prepare evaluations of contractor performance and submit them to the Past Performance Information Retrieval System (PPIRS). The CDC utilizes the Department of Defense (DOD) web-based Contractor Performance Assessment Reporting System (CPARS) to prepare and report these contractor performance evaluations. All information contained in these assessments may be used by the Government, within the limitations of FAR 42.15, for future source selections in accordance with FAR 15.304 where past performance is an evaluation factor.

The CPARS system requires a contractor representative to be assigned so that the contractor has appropriate input into the performance evaluation process. The CPARS contractor representative will be given access to CPARS and will be given the opportunity to concur or not-concur with performance evaluations before the evaluations are complete. The CPARS contractor representative will also have the opportunity to add comments to performance evaluations.

The assessment is not subject to the Disputes clause of the contract, nor is it subject to appeal beyond the review and comment procedures described in the guides on the CPARS website. Refer to: www.cpars.gov for details and additional information related to CPARS, CPARS user access, how contract performance assessments are conducted, and how Contractors participate. Access and training for all persons responsible for the preparation and review of performance assessments is also available at the CPARS website.

The contractor must provide the CDC contracting office with the name, e-mail address, and phone number of their designated CPARS representative who will be responsible for logging into CPARS and reviewing and commenting on performance evaluations. The contractor must maintain a current representative to serve as the contractor representative in CPARS. It is the contractor's responsibility to notify the CDC contracting office, in writing (letter or email), when their CPARS representative information needs to be changed or updated. Failure to maintain current CPARS contractor representative information will result in the loss of an opportunity to review and comment on performance evaluations.

(End of Clause)

Non-Disclosure Agreement for Contractor and Contractor Employees (May 2009)
The contractor shall prepare and submit a Non-Disclosure Agreement (NDA) to the Contracting Officer prior to access of government information or the commencement of work at CDC.

(a) The NDA made part of this clause, exhibit I and II, is required in service contracts where positions and/or functions proposed to be filled by contractor's employees will have access to non-public and procurement-sensitive information. The NDA also requires contractor's employees properly identify themselves as

employees of a contractor when communicating or interacting with CDC employees, employees of other governmental entities (when communication or interaction relates to the contractor's work with the CDC), and members of the public. The Federal Acquisition Regulation (FAR) 37.114 (c), states "All contractor personnel attending meetings, answering Government telephones, and working in other situations where their contractor status is not obvious to third parties are required to identify themselves as such to avoid creating an impression in the minds of members of the public or Congress that they are Government officials, unless, in the judgment of the agency, no harm can come from failing to identify themselves. They must also ensure that all documents or reports produced by contractors are suitably marked as contractor products or that contractor participation is appropriately disclosed."

(b) The Contractor shall inform employees of the identification requirements by which they must abide and monitor employee compliance with the identification requirements.

(c) During the contract performance period, the Contractor is responsible to ensure that all additional or replacement contractors' employees sign an NDA and it is submitted to the Contracting Officer prior to commencement of their work with the CDC.

(d) Contractor employees in designated positions or functions that have not signed the appropriate NDA shall not have access to any non-public, procurement sensitive information or participate in government meeting where sensitive information may be discussed.

(e) The Contractor shall prepare and maintain a current list of employees working under NDA's and submit to the Contracting Officer upon request during the contract period of performance. The list should at a minimum include: contract number, employee's name, position, date of hire and NDA requirement.

(End of Clause)

352.203-70 Anti-Lobbying. (December 18, 2015)
Pursuant to the HHS annual appropriations acts, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

(End of clause)

352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations. (December 18, 2015)

(a) In addition to complying with the clause at FAR 52.222-26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Health and Human Services (Agency) in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614. For purposes of this clause, the following definitions apply:

(1) Complaint means a formal or informal complaint that has been lodged with Agency management, Agency EEO officials, the Equal Employment Opportunity Commission (EEOC), or a court of competent jurisdiction.

(2) Contractor employee means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees, who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide the Agency with that employee's last known mailing address, e-mail address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

(3) Good faith cooperation cited in paragraph (a) includes, but is not limited to, making Contractor employees available for:

(i) Formal and informal interviews by EEO counselors or other Agency officials processing EEO complaints;

(ii) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;

(iii) Reviewing and signing appropriate affidavits or declarations summarizing statements provided by such Contractor employees during the course of EEO investigations;

(iv) Producing documents requested by EEO counselors, EEO investigators, Agency employees, or the EEOC in connection with a pending EEO complaint; and

(v) Preparing for and providing testimony in depositions or in hearings before the MSPB, EEOC and U.S. District Court.

(b) The Contractor shall include the provisions of this clause in all subcontract solicitations and subcontracts awarded at any tier under this contract.

(c) Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default.

(End of clause)

352.233-71 Litigation and Claims. (December 18, 2015)

(a) The Contractor shall provide written notification immediately to the Contracting Officer of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled "Allowable Cost and Payment."

(b) Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent documents received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect

an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action.

(c) If the Government undertakes a settlement or defense of an action or claim, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by other terms or conditions of this contract, by law or regulation, or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Government shall not reimburse or indemnify the Contractor for any liability loss, cost, or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

352.237-75 Key Personnel. (Dec 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of clause)

CDC AG001 – Invoice Submission (Jnl 2017)

(a) The Contractor shall submit the original contract invoice/voucher to the address shown below:

The Centers for Disease Control and Prevention Office of Financial Resources (OFR)
P.O. Box 15580
Atlanta, GA 30333

Or - The Contractor may submit the original invoice via facsimile or email:

Fax: 404-638-5324
Email: FMOAPINV@CDC.GOV
NOTE: Submit to only one (1) of the above locations.

(b) The contractor shall submit 2 copies of the invoice to the cognizant contracting office previously identified in this contract. These invoice copies shall be addressed to the attention of the Contracting Officer.

(c) The Contractor is , is not required to submit a copy of each invoice directly to the Contracting Officer's Representative (COR) concurrently with submission to the Contracting Officer.

(d) In accordance with 5 CFR part 1315 (Prompt Payment), CDC's Office of Financial Resources is the designated billing office for the purpose of determining the payment due date under FAR 32.904.

(e) The Contractor shall include (as a minimum) the following information on each invoice:

(1) Contractor's Name & Address
(2) Contractor's Tax Identification Number (TIN)
(3) Purchase Order/Contract Number and Task Order Number, as appropriate
(4) Invoice Number
(5) Invoice Date
(6) Contract Line Item Number (CLIN) and Description of Item
(7) Quantity
(8) Unit Price & Extended Amount for each line item
(9) Shipping and Payment Terms
(10) Total Amount of Invoice
(11) Name, title and telephone number of person to be notified in the event of a defective invoice
(12) Payment Address, if different from the information in I(1).
(13) DUNS + 4 Number
(14) Electronic funds transfer (EFT) banking information

(End of Clause)

Payment by Electronic Funds Transfer (Dec 2005)

(a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer – Central Contractor Registration, in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments

(b) In addition to Central Contractor Registration, the contractor shall make the designation by submitting the form titled "ACH Vendor/Miscellaneous Payment Enrollment Form" to the address indicated below. Note: The form is either attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer or the CDC Financial Management Office at (404) 498-4050.

(c) In cases where the contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required unless the designated financial institution has changed.

(d) The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address:

The Centers for Disease Control and Prevention
Financial Management Office (FMO)
P.O. Box 15580
Atlanta, GA 30333
Or – Fax copy to: 404-638-5324

(End of Clause)

508 Standard Requirements

All electronic and information technology (EIT) procured through this order must meet the applicable accessibility standards at 36 CFR 1194.22, unless an agency exception to this requirement exists. 36 CFR 1194 implements Section 508 of the Rehabilitation Act of 1973, as amended, and is viewable at http://www.access-board.gov/sec508/508 standards. htm - Section 1194.22.

The contractor shall indicate for each line item in the schedule whether each product or service is compliant or non-compliant with the accessibility standards at 36 CFR 1194.22. Further, the quote must indicate where full details of compliance can be found (i.e., vendor's website or other exact location).

(End of Clause)

352.211-3 Paperwork Reduction Act.

(a) This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Representative shall be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall not expend any funds or begin any data collection until the Contracting Officer provides the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

(End of clause)

EXHIBIT I
Centers for Disease Control and Prevention (CDC)
Contractor Non-Disclosure Agreement

I. Non-public Information

[Name of contractor] understands that in order to fulfill the responsibilities pursuant to **[Contract name and number]** between the Centers for Disease Control and Prevention and **[Name of CDC cootractor] dated [date],** employees of **[contractor]** will have access to non-public information, including confidential and privileged information contained in government-owned information technology systems. For purposes of this agreement, confidential information means government information that is not or will not be generally available to the public. Privileged information means information which cannot be disclosed without the prior written consent of the CDC.

In order to properly safeguard non-public information, **[contractor]** agrees to ensure that prior to being granted access to government information or the commencement of work for the CDC, whichever is applicable, all employees will sign a Non-Disclosure Agreement (NDA) provided by the CDC prior to beginning work for the CDC. Contractor agrees to submit to the contracting official the original signed copies of NDAs signed by the contractor's employees in accordance with the instructions provided by the contracting official. Failure to provide signed NDAs in accordance with this agreement and instructions provided by the contracting official could delay or prevent the employee from commencing or continuing work at the CDC until such agreement is signed and returned to the contracting official.

Contractor further agrees that it will not cause or encourage any employee to disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee any non-public information that the employee may obtain in connection with the performance of the employee's responsibilities to the CDC.

II. Procurement-Sensitive Information

Contractor further agrees that it will not cause or encourage any employee to disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual, other than an authorized Government employee, any procurement-sensitive information gained while in connection with fulfilling the employee's responsibilities at the CDC. For purposes of this agreement, procurement-sensitive information includes, but is not limited to, all information in Statements of Work (SOW), Requests for Contract (RFC), and Requests for Proposal (RFP); Responses to RFPs, including questions from potential Offerors; non-public information regarding procurements; all documents, conversations, discussions, data, correspondence, electronic mail (e-mail), presentations, or any other written or verbal communications relating to, concerning, or affecting proposed or pending solicitations or awards; procurement data; contract information plans; strategies; source selection information and documentation; offerors' identities; technical and cost data; the identity of government personal involved in the solicitation; the schedule of key technical and procurement events in the award determination process; and any other information that may provide an unfair competitive advantage to a contractor or potential contractor if improperly disclosed to them, or any of their employees.

Contractor understands and agrees that employee access to any procurement-sensitive information may create a conflict of interest which will preclude contractor from becoming a competitor for any acquisition(s) resulting from this information. Therefore, if an employee participates in any discussions relating to procurement-sensitive information, assists in developing any procurement-sensitive information, or otherwise obtains any procurement-sensitive information during the course of performing duties at the CDC, contractor understands and agrees that contractor may be excluded from competing for any acquisition(s) resulting from this information.

III. Identification of Non-Government Employees

Contractor understands that its employees are not agents of the Government. Therefore, unless otherwise directed in writing by the CDC, contractor agrees to assist and monitor employee compliance with the following identification procedures:

A. At the beginning of interactions with CDC employees, employees of other governmental entities, members of the public, or the media (when such communication or interaction relates to the contractor's work with the CDC), contractors' employees will identify themselves as an employee of a contractor.

B. Contractors' employees will include the following disclosures in all written communications, including outgoing electronic mail (e-mail) messages, in connection with contractual duties to the CDC:

Employee's name
Name of contractor
Center or office affiliation
Centers for Disease Control and Prevention

C. At the beginning of telephone conversations or conference calls, contractors' employees will identify themselves as an employee of a contractor.

D. Contractors should not wear any CDC logo on clothing, except for a CDC issued security badge while carrying out work for CDC or on CDC premises. The only other exception is when a CDC management official has granted permission to use the CDC logo.

E. Contractors' employees will program CDC voice mail message to identify themselves as an employee of a contractor.

I understand that federal laws including, 18 U.S.C. 641 and 18 U.S.C. 2071, provide criminal penalties for, among other things, unlawfully removing, destroying or converting to personal use, or use of another, any public records. Contractor acknowledges that contractor has read and fully understands this agreement.

Name of contractor: _____

Signature of Authorized Representative of Contractor: _____

Date: _____

Copies retained by: contracting official and contractor

EXHIBIT II
Centers for Disease Control and Prevention (CDC)
Contractors' Employee Non-Disclosure Agreement

I. Non-Public Information

I understand that in order to fulfill my responsibilities as an employee of **[Name of CDC contractor],** I will have access to non-public information, including confidential and privileged information contained in government-owned information technology systems. For purposes of this agreement, confidential information means government information that is not or will not be generally available to the public. Privileged information means information which cannot be disclosed without the prior written consent of the CDC.

I **[Name of Employee],** agree to use non-public information only in performance of my responsibilities to the CDC. I agree further that I will not disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee, any non-public information that I may obtain in connection with the performance of my responsibilities to the CDC.

II. Procurement-Sensitive Information

I further agree that unless I have prior written permission from the CDC, I will not disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee, any procurement-sensitive information gained in connection with the performance of my responsibilities to the CDC. I specifically agree not to disclose any non-public, procurement-sensitive information to employees of my company or any other organization unless so authorized in writing by the CDC. For purposes of this agreement, procurement-sensitive information includes, but is not limited to, all information in Statements of Work (SOW), Requests for Contract (RFC), and Requests for Proposal (RFP); Responses to RFPs, including questions from potential Offerors; non-public information regarding procurements; all documents, conversations, discussions, data, correspondence, electronic mail (e-mail), presentations, or any other written or verbal communications relating to, concerning, or affecting proposed or pending solicitations or awards; procurement data; contract information plans; strategies; source selection information and documentation; offerors' identities; technical and cost data; the identity of government personal involved in the acquisition; the schedule of key technical and procurement events in the award determination process; and any other information that may provide an unfair competitive advantage to a contractor or potential contractor if improperly disclosed to them, or any of their employees.

I understand and agree that my access to any procurement-sensitive information may create a conflict of interest which will preclude me, my current employer, or a future employer from becoming a competitor for any resulting government acquisition derived from this information. Therefore, if I participate in any discussions relating to procurement-sensitive information, assist in developing any procurement-sensitive information, or otherwise obtain any procurement-sensitive information during the course of performing my duties at the CDC, I understand and agree that I, my current employer, and any future employer(s) may be excluded from competing for any resulting acquisitions.

III. Special Non-Disclosure Clause for Contractors with Access to CDC Grants Management and Procurement-Related Information Technology Systems

In addition to complying with the non-disclosure requirements and safeguards stated above, I understand that my authorization to use CDC's grants management and procurement systems is strictly limited to the access and functions necessary for the performance of my responsibilities to the CDC and which have been approved in advance by the CDC. I understand that I am not authorized to enter procurement requests for any requirements pertaining to contracts or subcontracts held by me or my employer.

IV. Identification as a Non-Government Employee

I understand that as an employee of a government contractor, I represent an independent organization and I am not an agent of the Government. Therefore, I agree that unless I have prior written authorization from the CDC, I will, at

the beginning of interactions with CDC employees, employees of other governmental entities, members of the public, or the media (when such communication or interaction relates to the contractor's work with the CDC), identify myself as an employee of a contractor. I further agree to use the following identification procedures in connection with my work at the CDC:

A. I will include the following disclosures in all written communications, including outgoing electronic mail (e-mail) messages:

Employee's name
Name of contractor
Center or office Affiliation
Centers for Disease Control and Prevention

B. I will identify myself as an employee of a contractor at the beginning of telephone conversations or conference calls;
C. I will not wear any CDC logo on clothing, except for a CDC issued security badge while carrying out work for CDC or on CDC premises; the only other exception is when a CDC management official has granted permission to use the CDC logo.
D. I will program my CDC voice mail message to identify myself as a contractors' employee.

I understand that federal laws including, 18 U.S.C. 641 and 18 U.S.C. 2071, provide criminal penalties for, among other things, unlawfully removing, destroying or converting to personal use, or use of another, any public records. I acknowledge that I have read and fully understand this agreement.

Name of contractor: _____

Name of Employee: _____

Signature of Employee: _____

Date: _____

Copies retained by: contracting official, contractor, and Employee

APPENDIX I: Labor Category Breakout

(b)(4)