



**U.S. FOOD & DRUG  
ADMINISTRATION**

July 26, 2017

SUBJECT: Docket No. 030-04675; License No. 20-08361-01; Statement of Intent and Decommissioning Plan for the U.S. Food and Drug Administration Winchester Engineering and Analytical Center

Document Control Desk  
U.S. Regulatory Commission  
Washington, DC 20555-0001

U.S. Regulatory Commission Document Control Desk:

The U.S. Food and Drug Administration (FDA) Winchester Engineering and Analytical Center (WEAC) submits herein the *Statement of Intent (SOI)* pertaining to the decommissioning and remediation of soil areas located at 109 Holton Street, Winchester, Massachusetts.

On May 10, 2017, the FDA awarded a contract in the amount of \$432,752.73 (with an additional \$25,493.54 deep soil remediation option) to a third-party environmental firm, North Wind Solutions, located in Knoxville, Tennessee. The contract covers the scope of work described in the Decommissioning Plan included our submission dated July 21, 2017. Enclosed is the SOI for \$114,500 signed by the FDA's Deputy Commissioner for Operations (COO), which covers an additional 25% contingency referenced in the aforementioned submission.

We have also provided a courtesy copy of these files to Mr. Varughese Kurian, the NRC assigned project manager at 11545 Rockville Pike, Rockville, MD 20852.

WEAC and North Wind Solutions look forward to hosting meetings to answer any questions to expedite the review process. Please contact Elon Malkin, Assistant RSO and Decommissioning Project Manager, with any questions or comments regarding this submittal. He can be contacted at 781-756-9814 or by email at [Elon.Malkin@fda.hhs.gov](mailto:Elon.Malkin@fda.hhs.gov).

Sincerely,

Brian L. Baker -S  
2017.07.26 10:35:30 -04'00'

Brian L. Baker, P.E.  
Director, WEAC

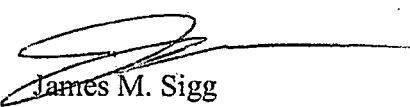
U.S. Food and Drug Administration  
Winchester Engineering & Analytical Center  
109 Holton Street  
Winchester, MA 01890  
[www.fda.gov](http://www.fda.gov)

NMSSDI  
NMSS

TO: U.S. Nuclear Regulatory Commission  
Washington, DC 20555

### STATEMENT OF INTENT

As Deputy Commissioner for Operations/COO of the U.S. Food and Drug Administration, I exercise express authority and responsibility to request from FDA funds for decommissioning activities associated with operations authorized by U.S. Nuclear Regulatory Commission Material License No. 20-08361-01. This authority is established by FDA Staff Manual Guide 1410.21 (enclosure 1). Within this authority, I intend to request that funds be made available when necessary to decommission for the purposes of partial site release the Winchester Engineering & Analytical Center, 109 Holton Street, Winchester, MA 01890. The FDA estimated the cost of this decommissioning for the partial site release to be \$458,000 and subsequently awarded a contract for same (enclosure 2). I intend to request and obtain the additional requisite 25% contingency funds (\$114,500) sufficiently in advance of decommissioning to prevent delay of required activities.



James M. Sigg  
Deputy Commissioner for Operations/COO  
Food and Drug Administration  
Date: 7/27/17

Attachment:  
FDA Staff Manual Guide 1410.21  
FDA Contract HHSF223201710022C

**SMG 1410.21**

**FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF  
AUTHORITY**

**REGULATORY – GENERAL REDELEGATIONS OF AUTHORITY**

**GENERAL REDELEGATIONS OF AUTHORITY FROM THE COMMISSIONER  
TO OTHER OFFICERS OF THE FOOD AND DRUG ADMINISTRATION**


Effective Date: September 21, 2016

**1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.**

- A. Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as referenced in the 1410 series of the Agency's Staff Manual Guides (SMGs). The Commissioner may continue to exercise all delegated authority referenced in these SMGs.
- B. The following officials are authorized to perform all delegable functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:
  - 1. Deputy Commissioner for Medical Products and Tobacco, Office of Medical Products and Tobacco (OMPT).
  - 2. Chief of Staff, Office of the Commissioner (OC).
  - 3. Deputy Commissioner for Operations and Chief Operating Officer, Office of Operations (OO).
  - 4. Deputy Commissioner for Policy, Planning, Legislation and Analysis, Office of Policy, Planning, Legislation and Analysis (OPPLA).
  - 5. Deputy Commissioner for Foods and Veterinary Medicine, Office of Foods and Veterinary Medicine (OFVM).
  - 6. Deputy Commissioner for Global Regulatory Operations and Policy, Office of Global Regulatory Operations and Policy (OGROP).
  - 7. Chief Scientist, Office of the Chief Scientist (OCS), OC.
  - 8. Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA), OGROP.

<b>SOLICITATION, OFFER, AND AWARD</b> (Construction, Alteration, or Repair)	1. SOLICITATION NO.	2. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input checked="" type="checkbox"/> NEGOTIATED (RFP)	3. DATE ISSUED	PAGE OF PAGES	
				1	43

IMPORTANT -- The "offer" section on the reverse must be fully completed by offeror.

4. CONTRACT NO. HHSF223201710022C		5. REQUISITION/PURCHASE REQUEST NO.	6. PROJECT NO.
7. ISSUED BY DHHS/FDA/OAGS/DAP ATTN: Daniel Weingarten 5630 Fishers Lane Room 2050 Rockville MD 20857	CODE DAP	8. ADDRESS OFFER TO North Wind Site Services, LLC 320 N. Cedar Bluff Road Knoxville, TN 37923	
9. FOR INFORMATION CALL: 	a. NAME DANIEL WEINGARTEN	b. TELEPHONE NO. (Include area code) (NO COLLECT CALLS) 240-402-7625	

### SOLICITATION

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder."

10. THE GOVERNMENT REQUIRES PERFORMANCE OF THE WORK DESCRIBED IN THESE DOCUMENTS (Title, identifying no., date)

Tax ID Number: 80-0805329

DUNS Number: 080381065

Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)

All items are accepted in Parts 1-3

11. The Contractor shall begin performance <u>10</u> calendar days and complete it within <u>240</u> calendar days after receiving <u>F-1</u>	
<input checked="" type="checkbox"/> award, <input type="checkbox"/> notice to proceed. The performance period is <input checked="" type="checkbox"/> mandatory <input type="checkbox"/> negotiable. (See <u>F-1</u> .)	
12a. THE CONTRACTOR MUST FURNISH ANY REQUIRED PERFORMANCE AND PAYMENT BONDS? (If "YES", indicate within how many calendar days after award in Item 12b.)	12b. CALENDAR DAYS <u>10</u>
13. ADDITIONAL SOLICITATION REQUIREMENTS:	
a. Sealed offers in original and _____ copies to perform the work required are due at the place specified in Item 8 by _____ (hour) local time (date). If this is a sealed bid solicitation, offers will be publicly opened at that time. Sealed envelopes containing offers shall be marked to show the offeror's name and address, the solicitation number, and the date and time offers are due.	
b. An offer guarantee <input type="checkbox"/> is, <input checked="" type="checkbox"/> is not required.	
c. All offers are subject to the (1) work requirements, and (2) other provisions and clauses incorporated in the solicitation in full text or by reference.	
d. Offers providing less than _____ calendar days for Government acceptance after the date offers are due will not be considered and will be rejected.	

## OFFER (Must be fully completed by offeror)

14. NAME AND ADDRESS OF OFFEROR (Include ZIP Code)

NORTH WIND SITE SERVICES, LLC 1507427  
 NORTH WIND SITE SERVICES, LLC  
 320 N CEDAR BLUFF RD STE 220  
 KNOXVILLE TN 379234524

15. TELEPHONE NO. (Include area code)

16. REMITTANCE ADDRESS (Include only if different than Item 14.)

CODE 1507427

FACILITY CODE

17. The offeror agrees to perform the work required at the prices specified below in strict accordance with the terms of this solicitation, if this offer is accepted by the Government in writing within \_\_\_\_\_ calendar days after the date offers are due. (Insert any number equal to or greater than the minimum requirement stated in item 13d. Failure to insert any number means the offeror accepts the minimum in item 13d.)

AMOUNTS

18. The offeror agrees to furnish any required performance and payment bonds.

## 19. ACKNOWLEDGEMENT OF AMENDMENTS

(The offeror acknowledges receipt of amendments to the solicitation -- give number and date of each)

AMENDMENT NO.										
DATE.										

20a. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)

20b. SIGNATURE

20c. OFFER DATE

## AWARD (To be completed by Government)

21. ITEMS ACCEPTED

Continued...

22. AMOUNT

\$432,752.73

23. ACCOUNTING AND APPROPRIATION DATA

24. SUBMIT INVOICES TO ADDRESS SHOWN IN  
(4 copies unless otherwise specified)ITEM  
G-3

25. OTHER THAN FULL AND OPEN COMPETITION PURSUANT TO

☐ 10 U.S.C. 2304(c) ( ) ☒ 41 U.S.C. 253(c) (5)

26. ADMINISTERED BY

CODE DAP

DHHS/FDA/OAGS/DAP  
 ATTN: Daniel Weingarten  
 5630 Fishers Lane  
 Room 2050  
 Rockville MD 20857

27. PAYMENT WILL BE MADE BY.

FDA PAYMENT SVCS  
 Attn: Vendor Payments, OFS FDA  
 10903 New Hampshire Avenue  
 Bldg 32, Rm 2162, Mail Hub 2145  
 Silver Spring MD 20993-0002

## CONTRACTING OFFICER WILL COMPLETE ITEM 28 OR 29 AS APPLICABLE

☐ 28. NEGOTIATED AGREEMENT

(Contractor is required to sign this document and return \_\_\_\_\_ copies to issuing office.)

Contractor agrees to furnish and deliver all items or perform all work requirements identified on this form and any continuation sheets for the consideration stated in this contract. The rights and obligations of the parties to this contract shall be governed by (a) this contract award, (b) the solicitation, and (c) the clauses, representations,

☒ 29. AWARD

(Contractor is not required to sign this document.)

Your offer on this solicitation is hereby accepted as to the items listed. This award consummates the contract, which consists of (a) the Government solicitation and your offer, and (b) this contract award. No further contractual document is necessary.

30a. NAME AND TITLE OF CONTRACTOR OR PERSON AUTHORIZED TO SIGN (Type or print)

31a. NAME OF CONTRACTING OFFICER (Type or print)

GINA K. JACKSON

30b. SIGNATURE

30c. DATE

31b. UNITED STATES OF AMERICA

31c. DATE

BY

STANDARD FORM 1442 (REV. 4-85) BACK

## CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED  
HHSF223201710022C

PAGE 3 OF 43

NAME OF OFFEROR OR CONTRACTOR  
NORTH WIND SITE SERVICES, LLC 1507427

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	The contractor shall perform the MARSSIM Remediation Survey in accordance with the attached contract documents at the following FDA Location:  Winchester Engineering & Analytical Center (WEAC) 109 Holton Street Winchester, MA 01890  COR: Robert Donovan FOB: Destination Period of Performance: 05/10/2017 to 01/05/2018				
1	MARSSIM SURVEY REDEMEDIATION Winchester Engineering and Analytical Center (WEAC) Obligated Amount: \$432,752.73				432,752.73
2	Optional Deeper Soil Samples Amount: \$25,493.54 (Option Line Item)  The total amount of award: \$458,246.27. The obligation for this award is shown in box 22.				0.00