



HHSAR Class Deviation 2025-01

MEMORANDUM TO: Heads of the Contracting Activities (HCA)

FROM: H. Katrina Brisbon *HKBrisbon*
HKBrisbon (Sep 30, 2024 15:39 EDT)
Deputy Assistant Secretary for Acquisitions and Senior Procurement Executive
Office of Acquisitions
Office of Assistant Secretary for Financial Resources (ASFR)
Department of Health and Human Services (HHS)

SUBJECT: Department of Health and Human Services Acquisition Regulation (HHSAR) Class Deviation No. 2025-01, Supply Chain Risk Assessments

1. **EFFECTIVE DATE:** October 1, 2024
2. **EXPIRATION DATE:** This class deviation is effective until either incorporated into the HHSAR, superseded, or otherwise rescinded.

3. PURPOSE:

This HHSAR class deviation implements supply chain risk assessments for mission-critical acquisitions.

4. BACKGROUND:

On December 19, 2022, the Deputy Secretary signed the HHS Supply Chain Risk (SCRM) Program Policy.

This class deviation is necessary for the purpose of immediately implementing policy in the HHSAR to comply with requirements of the HHS SCRM Program Policy.

41 U.S.C. 1707(a)(1) requires that a procurement policy, regulation, procedure, or form, including an amendment or modification, may not take effect until 60 days after it is published for public comment in the Federal Register if it “(A) relates to the expenditure of appropriated funds; and (B)(i) has a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form; or (ii) has a significant cost or administrative impact on contractors or offerors.”

To ensure the safety, security, integrity, and accessibility of HHS information, information systems, and associated information security, privacy, security, and supply chain risk management policy that is already deployed in the department, it is necessary to issue this class deviation in advance of a proposed rule to ensure it is properly and consistently included in HHS solicitations and contracts. It would seriously jeopardize the critical HHS mission if such policy were held in abeyance while a proposed rule was developed, and important public

comment and feedback were received and adjudicated. HHS intends on immediately developing a proposed rule for public comment to provide that opportunity after release of this class deviation.

5. GUIDANCE:

This requirement applies to all HHS Operating Divisions and Staff Divisions for applicable solicitations and contracts as set forth in the attached HHSAR deviation language.

Contracting officers shall comply with this class deviation to ensure the policy set forth in the attached HHSAR parts, subparts, sections, and subsections is followed, and any prescribed provisions or clauses are inserted, when applicable, in new solicitations issued and resultant contracts awarded on or after the effective date of the deviation.

Heads of the contracting activities (HCA) shall ensure this deviation is disseminated to the acquisition workforce, ensure compliance with the requirements in the class deviation, and ensure this class deviation is implemented in accordance with HHS Office of National Security guidance. ONS guidance and additional information is available at <https://intranet.hhs.gov/about-hhs/org-chart/ios/office-of-national-security>.

6. AUTHORITY:

This class deviation is issued under the authority of FAR 1.404, Class deviations, and HHSAR 301.401, Deviations, for the purpose of immediately implementing policy in the HHSAR via a class deviation to comply with requirements of the HHS SCRM Program Policy as set forth in the deviated language.

7. DEVIATION:

This class deviation adds subpart 304.73, Supply Chain Risk Assessments, to the HHSAR to implement the requirements for supply chain risk assessments when acquiring mission-critical items and services. (*See Summary of HHSAR Changes below.*)

SUMMARY OF HHSAR CHANGES. To implement the requirements, the HHSAR is deviated and revised, as summarized and provided in **Attachment 1** as follows:

- **Subpart 304.73—Supply Chain Risk Assessments. (Deviation).** This subpart is added to implement the requirements for supply chain risk assessments when acquiring mission-critical products, materials, information, or services.
- **304.7300 Scope of subpart. (Deviation).** This section is added to provide scope information pertaining to HHS supply chain risk assessment acquisitions.
- **304.7300-70 Applicability. (Deviation).** This subsection is added to provide when the subpart is applicable.
- **304.7301 Definitions. (Deviation).** This section is added to provide definitions of three terms used in the subpart.

- **304.7302 Policy. (Deviation).** This section is added to include a policy statement.
- **304.7303 Procedures. (Deviation).** This section is added as a header with no text.
- **304.7303-70 Supply chain risk assessment requirements. (Deviation).** This subsection is added to provide procedures for when and how supply chain risk assessments will be conducted.
- **304.7303-71 Supply chain risk assessment determinations. (Deviation).** This subsection is added to provide procedures for how the findings from the supply chain risk assessments will be used.
- **304.7304 Solicitation provision and contract clause. (Deviation).** This section is added to prescribe a new provision at 352.204-74, and a new clause at 352.204-75, for use in obtaining representations from offerors and contractors for use in the supply chain risk assessment.
- **Subpart 309.1—Responsible Prospective Contractors. (Deviation).** This subpart is added to implement the requirement for the use of special standards for HHS mission-critical acquisitions.
- **309.104 Standards. (Deviation).** This section is added as a header with no text.
- **309.104-2 Special Standards. (Deviation).** This subsection is added to provide procedures for the use of special standards for the procurement of mission-critical acquisitions.

8. CONTACT:

Acquisition workforce members with questions regarding this class deviation should contact their cognizant OpDiv/StaffDiv Acquisition Office or Acquisition Policy Council (APC) Representative(s), as appropriate.

The current list of APC Representatives may be found on the [Acquisition Councils and Workgroups Page](#) of the [HHS Acquisition Portal](#) (HHSAP).

All other questions should be directed to Acquisition_Policy@hhs.gov.

9. ATTACHMENT(S):

Attachment 1 – Class Deviation to the HHSAR: Supply Chain Risk Assessments

Class Deviation

to the

Department of Health and Human Services Acquisition Regulation (HHSAR): Supply Chain Risk Assessments

HHSAR Text Baseline is 48 CFR chapter 3 dated December 19, 2023.

Changes to baseline shown as [**bolded, bracketed additions**] and ~~strike through~~ deletions.

HHSAR text unchanged shown as asterisks.

**HHSAR PART 304—ADMINISTRATIVE AND [INFORMATION] MATTERS
[(DEVIATION)]**

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[Subpart 304.73—Supply Chain Risk Assessments. (Deviation)

304.7300 Scope of subpart. (Deviation)

304.7300-70 Applicability. (Deviation)

304.7301 Definitions. (Deviation)

304.7302 Policy. (Deviation)

304.7303 Procedures. (Deviation)

304.7303-70 Supply chain risk assessment requirements. (Deviation)

304.7303-71 Supply chain risk assessment determinations. (Deviation)

304.7304 Solicitation provision and contract clause. (Deviation)]

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[Subpart 304.73 – Supply Chain Risk Assessments. (Deviation)

304.7300 Scope of subpart. (Deviation)

This subpart implements, in part, various statutes, executive orders and policies, including Executive Order 14001 of January 21, 2021, A Sustainable Public Health Supply Chain; Executive Order 14017 of February 23, 2021, America’s Supply Chains; and the HHS Supply Chain Risk Management (SCRM) Program Policy requirement to conduct a supply chain risk assessment on mission-critical acquisitions.

304.7300-70 Applicability. (Deviation)

This subpart applies to solicitations and contracts for mission-critical acquisitions.

304.7301 Definitions. (Deviation)

As used in this subpart—

***Contract* means as defined in FAR 2.101.**

Foreign person means as defined in [31 CFR 800.224](#).

Mission-critical acquisition means the acquisition of products, materials, information, or services that are identified as—

(1) Contract support or development services for HHS or OpDiv/StaffDiv research and development;

(2) Contract support or development services for HHS or OpDiv/StaffDiv financial databases and services;

(3) Contract support services that require utilization or sharing of HHS or OpDiv/StaffDiv Intellectual property;

(4) Contract services supporting HHS or OpDiv/StaffDiv continuity of operations (COOP) mission essential functions;

(5) Contract support services or development initiatives for HHS or OpDiv/StaffDiv critical infrastructure;

(6) An HHS or OpDiv/StaffDiv high-value/dollar acquisition; or

(7) Other acquisitions for critical assets or services as identified by OpDiv/StaffDiv leadership.

Office of National Security (ONS) means the HHS office responsible for the management, oversight, policy, guidance, and implementation of the HHS Enterprise Supply Chain Risk Management (E-SCRM) Program, including the conducting of supply chain risk assessments.

State-owned enterprise means a legal entity that is created by a government in order to partake in commercial activities on the government's behalf. A state-owned enterprise or government-owned enterprise is a business enterprise where the government or state has significant control through full, majority, or significant minority ownership.

Supply chain risk means the potential for harm or compromise that arises as a result of security risks from suppliers, their supply chains, and their products, materials, information, or services. Supply chain risks include exposures, threats, and vulnerabilities associated with the products and services traversing the supply chain as well as the exposures, threats, and vulnerabilities to the supply chain.

Supply chain risk assessment (SCRA) means a systematic examination of supply chain risks, likelihoods of their occurrence, and potential impacts.

Supply chain risk management (SCRM) means a systematic process for managing risk to the integrity, trustworthiness, and authenticity of products, materials, information, and services within the supply chain. It addresses the activities of adversaries aimed at compromising the supply chain, which may include the introduction of counterfeit or

malicious items into the supply chain. It is conducted through identification of threats, vulnerabilities, and consequences throughout the supply chain and development of mitigation strategies to address the respective risks presented by the supplier, the supplied products, materials, information, and services, or the supply chain at any point during the life cycle.

304.7302 Policy.

HHS will conduct supply chain risk assessments on mission-critical acquisitions when required by ONS E-SCRM Program Policy to protect the Department's internal supply chain as it relates to threats posed by the activities of foreign and other adversaries toward the acquisition lifecycle of mission-critical products, materials, information, and services.

304.7303 Procedures.

304.7303-70 Supply chain risk assessment requirements.

(a) For mission-critical acquisitions, supply chain risk assessments—

(1) Will be conducted before award when required by ONS E-SCRM Program Policy, and

(2) May be conducted during contract performance when—

(A) There is an active supply chain risk mitigation in place;

(B) Adverse information is identified during performance;

(C) There are changes in reporting items in provision 352.204-74 or clause 352.204-75;

(D) The contract is modified to acquire mission-critical products, materials, information, or services;

(E) The Government plans to exercise an option period; or

(F) The contracting officer determines a supply chain risk assessment is needed after consultation with the appropriate SCRM personnel.

(b) ONS or a delegated OpDiv designee will perform the supply chain risk assessment using information submitted in response to the solicitation and other sources.

304.7303-71 Supply chain risk assessment determinations.

(a) Findings from the supply chain risk assessment will be considered in connection with a determination of the—

(1) offeror's responsibility and eligibility for award, or

(2) contractor's eligibility to continue performance on the contract.

(b) Failure to furnish the required information in provision 352.204-74 and clause 352.204-75 or additional information as requested by the contracting officer may render the—

(1) Offeror non-responsible and ineligible for award, or

(2) Contractor ineligible to continue performance on the contract.

304.7304 Solicitation provision and contract clause. (Deviation)

(a) The contracting officer shall insert the provision at 352.204-74, Supply Chain Risk Assessment, in solicitations for mission-critical acquisitions when required by ONS E-SCRM Program Policy.

(b) The contracting officer shall insert the clause at 352.204-75, Supply Chain Risk Assessment During Contract Performance, in solicitations and contracts for mission-critical acquisitions when required by ONS E-SCRM Program Policy.]

HHSAR PART 309 – CONTRACTOR QUALIFICATIONS [(DEVIATION)]

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[Subpart 309.1—Responsible Prospective Contractors. (Deviation)

309.104 Standards. (Deviation)

309.104-2 Special Standards. (Deviation)]

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[Subpart 309.1 – Responsible Prospective Contractors. (Deviation)

309.104 Standards. (Deviation)

309.104-2 Special Standards. (Deviation)

(a) A procurement that meets the definition of “mission-critical acquisition” as defined in HHSAR 304.7301 must meet special standards of responsibility which will be evaluated through a supply chain risk assessment as described in HHSAR 304.73, when required by ONS E-SCRM Program Policy. The contracting officer must ensure that these special standards are stated in the solicitation when applicable.]

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HHSAR PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

[(DEVIATION)]

Subpart 352.2—Text of Provisions and Clauses [(Deviation)]

[352.204-74 Supply Chain Risk Assessment (DEVIATION)]

As prescribed 304.7304(a) insert the following provision:

Supply Chain Risk Assessment (OCT 2024) (DEVIATION)

(a) Definitions. As used in this provision—

***Contract* means as defined in FAR 2.101.**

***Foreign person* means as defined in [31 CFR 800.224](#).**

***Mission-critical acquisition* means the acquisition of products, materials, information, or services that are identified as—**

(1) Contract support or development services for HHS or OpDiv/StaffDiv research and development;

(2) Contract support or development services for HHS or OpDiv/StaffDiv financial databases and services;

(3) Contract support services that require utilization or sharing of HHS or OpDiv/StaffDiv Intellectual property;

(4) Contract services supporting HHS or OpDiv/StaffDiv continuity of operations (COOP) mission essential functions;

(5) Contract support services or development initiatives for HHS or OpDiv/StaffDiv critical infrastructure;

(6) An HHS or OpDiv/StaffDiv high-value/dollar acquisition; or

(7) Other acquisitions for critical assets or services as identified by OpDiv/StaffDiv leadership.

***Office of National Security (ONS)* means the HHS office responsible for the management, oversight, policy, guidance, and implementation of the HHS Enterprise Supply Chain Risk Management (E-SCRM) Program, including the conducting of supply chain risk assessments.**

***State-owned enterprise* means a legal entity that is created by a government in order**

to partake in commercial activities on the government's behalf. A state-owned enterprise or government-owned enterprise is a business enterprise where the government or state has significant control through full, majority, or significant minority ownership.

Supply chain risk means the potential for harm or compromise that arises as a result of security risks from suppliers, their supply chains, and their products, materials, information, or services. Supply chain risks include exposures, threats, and vulnerabilities associated with the products and services traversing the supply chain as well as the exposures, threats, and vulnerabilities to the supply chain.

Supply chain risk assessment means a systematic examination of supply chain risks, likelihoods of their occurrence, and potential impacts.

Supply chain risk management (SCRM) means a systematic process for managing risk to the integrity, trustworthiness, and authenticity of products, materials, information, and services within the supply chain. It addresses the activities of foreign and other adversaries aimed at compromising the supply chain, which may include the introduction of counterfeit or malicious items into the supply chain. It is conducted through identification of threats, vulnerabilities, and consequences throughout the supply chain and development of mitigation strategies to address the respective risks presented by the supplier, the supplied products, materials, information, and services, or the supply chain at any point during the life cycle.

(b) *Supply chain risk assessment.* The Office of National Security (ONS) or delegated designee may perform a supply chain risk assessment of the Offeror's proposal. In performing the supply chain risk assessment, the Government may consider public and non-public information relating to the Offeror's supply chain.

(c) *Required information submittal.* The Offeror shall provide the following information for products, materials, information, or services provided under their proposal:

(1) Description of the type of products, materials, information, or services provided.

(2) Vendor and manufacturer's company, if applicable, including name and address.

(3) If known, vendor's and manufacturer's web site, and the Commercial and Government Entity (CAGE) code and Unique Entity Identifier (UEI).

(d) *Representations.* The Offeror represents that—

(1) It does, does not have any foreign ownership, outside of retail shareholders, who control more than 10% of the company's total shares. If yes, identify the legal name of the owning organization/individual and their country of affiliation.

(2) It does, does not have any of the following business affiliations with foreign entities: technology development partnerships, strategic partnerships, joint ventures, foreign subsidiaries, grants from a foreign entity. If yes, identify the legal name of the organization, its foreign address, and the nature of the relationship.

(3) It does, does not have any foreign governments, or state-owned enterprises that have investments or ownership interest in the company. If yes, identify the foreign government, the ownership stake percentage, and the nature of the relationship.

(4) The company leadership (C-Suite executives, Board members, etc.) does, does not have any substantial ties to foreign countries, including being citizens of a foreign country, graduates of a foreign university, or investments in a foreign country. If yes, identify the individual, the nature of the tie, and the country they are tied to.

(5) It has, has not violated export controls or the Foreign Corrupt Practices Act within 5 years. If yes, enter the event, the date, and any remediation the company committed after the event.

(6) It has, has not been prohibited from doing business with the government of the US or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and any remediation the company committed after the event.

(7) It has, has not been prohibited from doing business with any foreign governments or subdivisions thereof. If yes, enter the event, the date, and any remediation the company committed after the event.

(8) It has had, has not had affiliations with any entities prohibited (e.g. Huawei, see SAM.gov "exclusions" page for additional information regarding prohibited entities) from doing business with the government of the US or any of its administrative

subdivisions to include agencies, states, territories or municipalities? If yes, enter the event, the date, and any remediation the company committed after the event.

(9) It [] has, [] has not been suspended or debarred at any point while doing business with the U.S. Government or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and details below.

(10) It [] has previously filed for or is currently in, [] has not previously filed for or is not currently in bankruptcy in the last 10 years. If yes, enter the event, the date, and details below.

(11) It [] was or is currently in, [] was not or is not currently in litigation in the last 10 years. If yes, enter the event, the date, and details below.

(e) *Supply chain risk determination.* Findings from the supply chain risk assessment will be considered in connection with a determination of the Offeror's responsibility and eligibility for award. Failure of the Offeror to furnish the information required in this provision or provide additional information as requested by the Contracting Officer may render the Offeror non-responsible and ineligible for award. The Government reserves the right to limit the disclosure of information to the Offeror regarding the risk in accordance with all applicable laws or regulations.

(f) *Mitigation plans.* Any mitigation plans and amendments determined necessary and to be implemented and sustained during contract performance will be incorporated into the contract.

(g) *Subcontracts.* The Offeror shall include the substance of this provision, including the information and representations at paragraphs (c) and (d), and including this paragraph (g), in subcontracts with persons or entities proposed to be used involving the development or delivery of any mission-critical products, materials, information, or services. The Offeror shall submit all potential subcontractor information and representations with its proposal for any mission-critical products, materials, information, or services provided for in the proposal.

(End of provision)

352.204-75 Supply Chain Risk Assessment During Contract Performance (DEVIATION)

As prescribed in 304.7304(b) insert the following clause:

Supply Chain Risk Assessment During Contract Performance (OCT 2024) (DEVIATION)

(a) *Definitions.* As used in this clause—

Contract means as defined in FAR 2.101.

Foreign person means as defined in [31 CFR 800.224](#).

Mission-critical acquisition means the acquisition of products, materials, information, or services that are identified as—

(1) Contract support or development services for HHS or OpDiv/StaffDiv research and development;

(2) Contract support or development services for HHS or OpDiv/StaffDiv Financial databases and services;

(3) Contract support services that require utilization or sharing of HHS or OpDiv/StaffDiv Intellectual property;

(4) Contract services supporting HHS or OpDiv/StaffDiv continuity of operations (COOP) mission essential functions;

(5) Contract support services or development initiatives for HHS or OpDiv/StaffDiv critical infrastructure;

(6) An HHS or OpDiv/StaffDiv high-value/dollar acquisition; or

(7) Other acquisitions for critical assets or services as identified by OpDiv/StaffDiv leadership.

Office of National Security (ONS) means the HHS office responsible for the management, oversight, policy, guidance, and implementation of the HHS Enterprise Supply Chain Risk Management (E-SCRM) Program, including the conducting of supply chain risk assessments.

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Supply chain risk means the potential for harm or compromise that arises as a result of security risks from suppliers, their supply chains, and their products, materials, information, or services. Supply chain risks include exposures, threats, and vulnerabilities associated with the products and services traversing the supply chain as well as the

exposures, threats, and vulnerabilities to the supply chain.

Supply chain risk assessment means a systematic examination of supply chain risks, likelihoods of their occurrence, and potential impacts.

Supply chain risk management (SCRM) means a systematic process for managing risk to the integrity, trustworthiness, and authenticity of products, materials, information, and services within the supply chain. It addresses the activities of foreign and other adversaries aimed at compromising the supply chain, which may include the introduction of counterfeit or malicious items into the supply chain. It is conducted through identification of threats, vulnerabilities, and consequences throughout the supply chain and development of mitigation strategies to address the respective risks presented by the supplier, the supplied products, materials, information, and services, or the supply chain at any point during the life cycle.

(b) *Supply chain risk assessment.* The Office of National Security (ONS) or delegated designee may perform a supply chain risk assessment of the Contractor. In performing the supply chain risk assessment, the Government may consider public and non-public information relating to the Contractor's supply chain.

(c) *Updated information and representations.* If requested by the Contracting Officer, or if there are any changes to the information or representations the Contractor has submitted prior to award or during contract performance, the Contractor must submit to the Contracting Officer the information and representations in paragraphs (d) or (e).

(d) *Required information submittal.* The Contractor shall provide the following information for products, materials, information, or services provided during contract performance:

(1) Description of the type of products, materials, information, or services provided.

(2) Vendor and manufacturer's company, if applicable, including name and address.

(3) If known, vendor's and manufacturer's web site, and the Commercial and Government Entity (CAGE) code and Unique Entity Identifier (UEI).

(e) *Representations.* The Contractor represents that—

(1) It does, does not have any foreign ownership, outside of retail shareholders, who control more than 10% of the company's total shares. If yes, identify the legal name of the owning organization/individual and their country of affiliation.

(2) It does, does not have any of the following business affiliations with foreign entities: technology development partnerships, strategic partnerships, joint ventures, foreign subsidiaries, grants from a foreign entity. If yes, identify the legal name of the organization, its foreign address, and the nature of the relationship.

(3) It does, does not have any foreign governments, or state-owned enterprises that have investments or ownership interest in the company. If yes, identify the foreign government, the ownership stake percentage, and the nature of the relationship.

(4) The company leadership (C-Suite executives, Board members, etc.) does, does not have any substantial ties to foreign countries, including being citizens of a foreign country, graduates of a foreign university, or investments in a foreign country. If yes, identify the individual, the nature of the tie, and the country they are tied to.

(5) It has, has not violated export controls or the Foreign Corrupt Practices Act within 5 years. If yes, enter the event, the date, and any remediation the company committed after the event.

(6) It has, has not been prohibited from doing business with the government of the US or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and any remediation the company committed after the event.

(7) It has, has not been prohibited from doing business with any foreign governments or subdivisions thereof. If yes, enter the event, the date, and any remediation the company committed after the event.

(8) It has had, has not had affiliations with any entities prohibited (e.g. Huawei, see SAM.gov "exclusions" page for additional information regarding prohibited entities) from doing business with the government of the US or any of its administrative

subdivisions to include agencies, states, territories or municipalities? If yes, enter the event, the date, and any remediation the company committed after the event.

(9) It [] has, [] has not been suspended or debarred at any point while doing business with the U.S. Government or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and details below.

(10) It [] has previously filed for or is currently in, [] has not previously filed for or is not currently in bankruptcy in the last 10 years. If yes, enter the event, the date, and details below.

(11) It [] was or is currently in, [] was not or is not currently in litigation in the last 10 years. If yes, enter the event, the date, and details below.

(f) *Supply chain risk determination.* Findings from the supply chain risk assessment will be considered in connection with a determination of the Contractor's eligibility to continue performance on the contract. The Government reserves the right to limit the disclosure of information to the Offeror regarding the risk in accordance with all applicable laws or regulations.

(g) *Mitigation plans.* Any mitigation plans and amendments determined necessary and to be implemented and sustained during contract performance will be incorporated into the contract.

(h) *Subcontracts.* The Contractor shall include the substance of this clause, including the information and representations in paragraphs (d) and (e), and this paragraph (h), in subcontracts with persons or entities involved the development or delivery of any mission-critical products, materials, information, or services. The Contractor shall submit all subcontractor information and representations with its proposal for any additional mission-critical products, materials, information, or services during performance of the contract.

(End of clause)]