

Request for Records Disposition Authority

Records Schedule Number: DAA-0468-2013-0003
 Schedule Status: Modified Approved Version
 Agency or Establishment: Department of Health and Human Services
 Record Group / Scheduling Group: General Records of the Department of Health and Human Services
 Records Schedule applies to: Major Subdivision
 Major Subdivision: Office of the Secretary
 Minor Subdivision: Office of the Assistant Secretary for Preparedness and Response
 Schedule Subject: Medical Countermeasures Records
 Internal agency concurrences will be provided: Yes

Background Information

These records relate to the Assistant Secretary for Preparedness and Response's role in the Department of Health and Human Services' preparedness towards medical countermeasures against chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza, and emerging infectious diseases.

Within the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Biological Advanced Research and Development Authority (BARDA), the Office of Policy and Planning (OPP) and the Office of Acquisitions, Management, Contracts, and Grants (AMCG) perform active and supporting roles in developing and acquiring medical countermeasures against CBRN threats, pandemic influenza, and emerging infectious diseases.

ASPR's Medical countermeasure development and acquisition activities are defined by the Pandemic and All Hazards Preparedness Act (PAHPA) of 2006 and Project BioShield Act of 2003; both pieces of legislation were renewed in 2013 under Pandemic and All Hazards Preparedness Reauthorization Act (PAHPRA) and provide a comprehensive listing of mission responsibilities.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
7	5	2	0

GAO Approval

Outline of Records Schedule Items for DAA-0468-2013-0003

Sequence Number	
1	Medical Countermeasure Project Records
1.1	Medical Countermeasure Advanced Development Activity Records Disposition Authority Number: DAA-0468-2013-0003-0001
1.2	Medical Countermeasure Project Acquisition Records Disposition Authority Number: DAA-0468-2013-0003-0002
2	Medical Countermeasure Regulatory Records Disposition Authority Number: DAA-0468-2013-0003-0003
3	Manufacturing, Facilities and Engineering Records Disposition Authority Number: DAA-0468-2013-0003-0004
4	Analytical Decision Support Activity Records Disposition Authority Number: DAA-0468-2013-0003-0005
5	Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Records
5.1	PHEMCE Working Group, Team, Council and Committee Records Disposition Authority Number: DAA-0468-2013-0003-0006
5.2	PHEMCE Stakeholder Engagement Records Disposition Authority Number: DAA-0468-2013-0003-0007

How frequently will your agency transfer these records to the National Archives? **Every 4 Years**

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	30 GB	
Paper		
Microform		
Hardcopy or Analog Special Media		

1.2

Medical Countermeasure Project Acquisition Records

Disposition Authority Number **DAA-0468-2013-0003-0002**

Records relating to the procurement of safe and effective medical countermeasures to protect and treat the population in the event of public health emergencies caused by bioterrorism, pandemic influenza, or emerging infectious diseases, including, but not limited to, project files and support documentation. Medical countermeasure project acquisition records do not include any confidential or proprietary information from the contract file. Project records are stored both in an electronic repository and in paper copy, maintained by the Biological Advanced Research and Development Authority (BARDA).

Final Disposition **Permanent**

Item Status **Active**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **Yes**

Do any of the records covered by this item exist as structured electronic data? **No**

Disposition Instruction

Cutoff Instruction **Cut off at the end of the calendar year in which the related contract file is closed.**

Transfer to Inactive Storage **Transfer paper records to the Federal Records Center five years after cutoff.**

Transfer to the National Archives for Accessioning

Transfer paper records in four year blocks when the most recent records in the block are 15 years old. Transfer electronic records in four year blocks when the earliest records in the block are 5 years old.

Additional Information

What will be the date span of the initial transfer of records to the National Archives?

From 2004 To 2008

How frequently will your agency transfer these records to the National Archives?

Every 4 Years

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	80 GB	
Paper		
Microform		
Hardcopy or Analog Special Media		

2

Medical Countermeasure Regulatory Records

Disposition Authority Number **DAA-0468-2013-0003-0003**

Medical countermeasure regulatory activities ensure the availability and delivery of safe, effective, and quality medical countermeasures needed in a time of public health emergency and minimize the risks inherent in the regulatory process for Federal investments of BARDA-sponsored medical countermeasures. Regulatory records pertaining to the regulatory review and approval process of medical countermeasures include, but are not limited to, Investigational New Drug (IND) applications, Emergency Use Authorizations (EAUs), Reports of Site Audits, Records of Review (ROR), and quality performance measures. Records are stored both in an electronic repository and in secure paper copy, maintained by BARDA.

Final Disposition **Temporary**

Item Status **Active**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **Yes**

3

Do any of the records covered by this item exist as structured electronic data?	No
Disposition Instruction	
Cutoff Instruction	Cut off at the end of the calendar year in which the records are submitted or finalized.
Transfer to Inactive Storage	Transfer paper records to the Federal Records Center five years after cutoff.
Retention Period	Destroy 75 year(s) after cutoff
Additional Information	
GAO Approval	Not Required
Manufacturing, Facilities and Engineering Records	
Disposition Authority Number	DAA-0468-2013-0003-0004
<p>Records supporting the building or retrofitting of the U.S. manufacturing infrastructure to enable the rapid production of vaccines and other biologics against pandemic influenza and other emerging threats. Records for public-private partnership programs, such as the Centers for Innovation and Advanced Development and Manufacturing (CIADM), are also included. These records include, but are not limited to contractor produced records such as milestone and deliverable reports and technical review reports that are specified in the contract as the property of the U.S. Government. These records are stored in an electronic repository and managed by the Biological Advanced Research and Development Authority (BARDA).</p>	
Final Disposition	Permanent
Item Status	Active
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
Do any of the records covered by this item exist as structured electronic data?	No
Disposition Instruction	
Cutoff Instruction	Cut off at the end of the calendar year in which the related contract file is closed.
Transfer to Inactive Storage	Transfer paper records to the Federal Records Center five years after cutoff.

Transfer to the National Archives for Accessioning

Transfer paper records in four year blocks when the most recent records in the block are 15 years old. Transfer electronic records in four year blocks when the earliest records in the block are 5 years old.

Additional Information

What will be the date span of the initial transfer of records to the National Archives?

From 2004 To 2008

How frequently will your agency transfer these records to the National Archives?

Every 4 Years

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	12 GB	
Paper		
Microform		
Hardcopy or Analog Special Media		

4

Analytical Decision Support Activity Records

Disposition Authority Number **DAA-0468-2013-0003-0005**

The Analytic Decision Support Activity Records document the development of analyses, processes and decision support systems for medical and public health consequence assessments and public health response capabilities across the chemical, biological, radiological, nuclear, pandemic influenza, and emerging infectious diseases risk-spectrum. These activities support decisions leading to measurable improvements in public health preparedness. The source data for developing these analyses includes, but is not limited to, subject matter expert elicitations, open source records and Department of Homeland Security Material Threat Assessment exposure files. Analytical Decision Support Activity records include the finalized products that inform the decision-making process for BARDA, PHEMCE, ASPR and HHS. These records include, but are not limited to, medical and public health consequence modeling reports, medical public health consequence modeling presentations and the associated dossier for medical and public health consequence modeling studies. These records are maintained by the Biological Advanced Research and Development Authority (BARDA).

Final Disposition

Permanent

Item Status **Active**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **Yes**

Do any of the records covered by this item exist as structured electronic data? **No**

Disposition Instruction

Cutoff Instruction **Cutoff at the end of the fiscal year in which the report is published or when the document is finalized and distributed.**

Transfer to Inactive Storage **Transfer paper records to the Federal Records Center five years after cutoff.**

Transfer to the National Archives for Accessioning **Transfer paper records in four year blocks when the most recent records in the block are 15 years old. Transfer electronic records in four year blocks when the earliest records in the block are 5 years old.**

Additional Information

What will be the date span of the initial transfer of records to the National Archives? **From 2004 To 2008**

How frequently will your agency transfer these records to the National Archives? **Every 4 Years**

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	10 GB	
Paper		
Microform		
Hardcopy or Analog Special Media		

5 **Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Records**
PHEMCE serves as the Federal interagency coordinating organization for medical countermeasure requirements, policy and strategy development, prioritization,

stockpiling and effective utilization. The PHEMCE is led by the Assistant Secretary for Preparedness and Response (ASPR) with core HHS members from BARDA, CDC, NIAID within NIH and FDA. Key PHEMCE interagency partners include the VA, DoD, DHS and USDA. Core planning activities performed by PHEMCE include, but are not limited to, establishing requirements for civilian medical countermeasures, medical countermeasure preparedness assessment, establishing and prioritizing medical countermeasure requirements, research and development and planning for the acquisition, stockpiling, distribution and utilization of medical countermeasures.

5.1

PHEMCE Working Group, Team, Council and Committee Records

Disposition Authority Number **DAA-0468-2013-0003-0006**

Records of the Interagency Working Groups (WGs), Integrated Product Teams (IPTs), Enterprise Senior Council (ESC) and the Enterprise Executive Committee (EEC). These records are used to establish requirements for civilian medical countermeasures medical countermeasure preparedness assessment, establishing and prioritizing medical countermeasure requirements, research and development and planning for the acquisition, stockpiling, distribution and utilization of medical countermeasures. These records include meeting summaries, briefing materials and slide presentations, background and supporting documents such as modeling data, policy white papers, strategic implementation plans, and planning and decision analysis documents such as Scenario Based Analysis and Product Specific Requirements documents. These records are maintained by the Office of Policy and Planning (OPP) and provide the basis for policy decisions and development.

Final Disposition **Permanent**

Item Status **Inactive**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **Yes**

Do any of the records covered by this item exist as structured electronic data? **No**

Inactive Status Explanation **This item is inactive because it was superseded by New Disposition Authority Number: DAA-0468-2015-0001-0004**

Disposition Instruction

Cutoff Instruction **Cutoff at the end of the fiscal year in which the document is created**

Transfer to Inactive Storage

Transfer paper records to the Federal Records Center five years after cutoff.

Transfer to the National Archives for Accessioning

Transfer paper records in four year blocks when the most recent records in the block are 15 years old. Transfer electronic records in four year blocks when the earliest records in the block are 5 years old.

Additional Information

What will be the date span of the initial transfer of records to the National Archives?

From 2006 To 2010

How frequently will your agency transfer these records to the National Archives?

Every 4 Years

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	5 GB	
Paper	20 Cubic feet	
Microform		
Hardcopy or Analog Special Media		

5.2

PHEMCE Stakeholder Engagement Records

Disposition Authority Number DAA-0468-2013-0003-0007

Workshops, conferences, focus groups and meetings materials that specifically supports the generation of medical countermeasure requirements, or planning for effective utilization of medical countermeasures. These records include, but are not limited to, presentations, agendas, webcasts, meeting materials, participant lists and reports that are used to develop policies. These records are maintained by the Office of Policy and Planning (OPP).

Final Disposition

Temporary

Item Status

Inactive

Is this item media neutral?

Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?

Yes

Do any of the records covered by this item exist as structured electronic data?	No
Inactive Status Explanation	This item is inactive because it was superseded by New Disposition Authority Number: DAA-0468-2015-0001-0003
Disposition Instruction	
Cutoff Instruction	Cut off at the end of the fiscal year in which the document is created.
Transfer to Inactive Storage	Transfer paper records to the Federal Records Center five years after cutoff.
Retention Period	Destroy 10 year(s) after cutoff
Additional Information	
GAO Approval	Not Required

Agency Certification

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal in this schedule are not now needed for the business of the agency or will not be needed after the retention periods specified.

Signatory Information

Date	Action	By	Title	Organization
12/21/2012	Certify	Elaine Pankey	Records Officer	Offices of the Secretary - OCIO
04/09/2013	Return for Revision	Valerie Terray	Archives Specialist	National Archives and Records Administration - Records Management Services
05/21/2013	Submit For Certification	Elaine Pankey	HHS Office of the Secretary Records Officer	Offices of the Secretary, Assistant Secretary for Administration - Office of the Chief Information Officer
05/21/2013	Certify	Elaine Pankey	HHS Office of the Secretary Records Officer	Offices of the Secretary, Assistant Secretary for Administration - Office of the Chief Information Officer
06/06/2013	Return for Revision	Valerie Terray	Archives Specialist	National Archives and Records Administration - Records Management Services
06/06/2013	Submit For Certification	Elaine Pankey	HHS Office of the Secretary Records Officer	Offices of the Secretary, Assistant Secretary for Administration - Office of the Chief Information Officer
06/06/2013	Certify	Elaine Pankey	HHS Office of the Secretary Records Officer	Offices of the Secretary, Assistant Secretary for Administration - Office of the Chief Information Officer

10/22/2013	Submit for Concurrency	Valerie Terray	Archives Specialist	National Archives and Records Administration - Records Management Services
10/22/2013	Concur	Laurence Brewer	Director, National Records Management Program	National Archives and Records Administration - National Records Management Program
10/22/2013	Concur	Laurence Brewer	Director, National Records Management Program	National Archives and Records Administration - National Records Management Program
10/24/2013	Approve	David Ferriero	Archivist of the United States	Office of the Archivist - Office of the Archivist