



441 G St. N.W.  
Washington, DC 20548

July 7, 2017

Congressional Committees

**Chemical and Biological Defense: DOD Has Identified an Infrastructure Manager and Is Developing the Position’s Roles and Responsibilities**

Over the past 4 years, the United States has faced significant chemical and biological threats to its national security. North Korea’s weapons of mass destruction program, according to the *Quadrennial Defense Review 2014*, constitutes a significant threat to peace and stability on the Korean Peninsula and in Northeast Asia, and is a growing and direct threat to the United States.<sup>1</sup> Moreover, the use of chemical weapons in Syria in August 2013 and again in April 2017, the 2014 Ebola virus outbreak in West Africa, the 2015-2016 Zika virus outbreak in the Americas, the ongoing threat from influenza strains like H5N1 (avian influenza or “bird flu”), and the emergence of nontraditional (chemical) agents, have each, among others, highlighted the nation’s potential vulnerability to chemical and biological attacks and naturally occurring diseases.<sup>2</sup> Additionally, the spread of scientific knowledge and capabilities by state and nonstate actors to produce effective chemical and biological weapons further contributes to the nation’s vulnerability.

The Department of Defense’s (DOD) Chemical and Biological Defense Program (CBDP) leads the department’s efforts to develop solutions, such as countermeasures, “to enable the warfighter to deter, prevent, protect against, mitigate, respond to, and recover from chemical, biological, radiological, and nuclear (CBRN) threats and effects as part of a layered, integrated defense.”<sup>3</sup> The CBDP Enterprise—comprising DOD’s chemical and biological defense research and development and test and evaluation infrastructure found among 26 DOD organizations—is responsible for implementing this mission. These organizations determine warfighter requirements, provide science and technology expertise, conduct research and development, and perform test and evaluation on capabilities needed to protect the warfighter, and provide

<sup>1</sup> DOD, *Quadrennial Defense Review 2014* (Washington, D.C.: Mar. 4, 2014).

<sup>2</sup> As of January 2017, the World Health Organization confirmed 856 human cases of H5N1 infection worldwide between 2003 and 2017, and almost 53 percent of those infections were fatal. See GAO, *Emerging Infectious Diseases: Preliminary Observations on the Zika Virus Outbreak*, [GAO-16-470T](#) (Washington, D.C.: Mar. 2, 2016) and *Defense Civil Support: DOD, HHS, and DHS Should Use Existing Coordination Mechanisms to Improve Their Pandemic Preparedness*, [GAO-17-150](#) (Washington, D.C.: Feb. 10, 2017). In addition, nontraditional (chemical) agents are chemicals reportedly researched or developed with potential application or intent for use as chemical warfare agents that do not fall into the category of traditional chemical warfare agents, toxic industrial chemicals, or toxic industrial materials.

<sup>3</sup> DOD, *Chemical and Biological Defense Program (CBDP) Strategic Plan* (June 15, 2012).

oversight.<sup>4</sup> In addition to DOD, several other federal departments and agencies have responsibilities as part of their mission for assessing the threat of biological and chemical agents and determining requirements and priorities for developing and obtaining countermeasures for these agents. These other federal agencies include the Department of Health and Human Services' Centers for Disease Control and Prevention, the National Institutes of Health, the Food and Drug Administration, and the Department of Homeland Security's National Biodefense Analysis and Countermeasures Center.

In our June 2015 report on DOD's efforts to manage the department's chemical and biological infrastructure capabilities, we recommended, among other things, that DOD (1) designate an entity to lead the effort to identify required infrastructure; (2) identify, request, and consider any information from chemical and biological infrastructure studies of other federal agencies to avoid potential duplication; and (3) update the CBDP Enterprise's guidance and planning process to fully institutionalize the use of risk assessments.<sup>5</sup> DOD concurred with these recommendations and, as of May 2017, had implemented our recommendation to designate an entity to lead the effort to identify required infrastructure and had begun actions to implement the other two recommendations.

In House Conference Report 114-270, the House and Senate conferees required DOD to report to the congressional defense committees on the designation of an individual responsible for managing the infrastructure for the CBDP in order to minimize duplication of effort both within DOD and other agencies of the federal government.<sup>6</sup> The House and Senate conferees noted that this was consistent with the findings and recommendations in our June 2015 report and included a provision that we review the roles and responsibilities of the official designated to be responsible for infrastructure management.<sup>7</sup> This report describes the status of DOD's efforts to develop the roles and responsibilities of DOD's CBDP Infrastructure Manager.

We reviewed the departmental and U.S. Office of Personnel Management criteria that DOD officials used to develop the roles and responsibilities for DOD's CBDP Infrastructure Manager and DOD guidance (e.g., directives and instructions) from similar organizations under the Office of the Under Secretary of Defense for Acquisition, Technology and Logistics and Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs partners.<sup>8</sup> This guidance comes from and includes, but is not limited to, the following organizations: (1) Under Secretary of Defense for Acquisition, Technology and Logistics' Test

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<sup>4</sup> Some of the key organizations that comprise the CBDP Enterprise include the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs; the Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense; the Joint Program Executive Office for Chemical and Biological Defense; the U.S. Army Test and Evaluation Command; the U.S. Army Medical Research Institute of Infectious Diseases; the Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense; and the Defense Threat Reduction Agency. See GAO, *Chemical and Biological Defense: Designated Entity Needed to Identify, Align, and Manage DOD's Infrastructure*, [GAO-15-257](#) (Washington, D.C.: June 25, 2015).

<sup>5</sup> [GAO-15-257](#).

<sup>6</sup> H.R. Conf. Rep. No. 114-270 at 624 (2015), accompanying H.R. 1735, a proposed bill for the National Defense Authorization Act for Fiscal Year 2016.

<sup>7</sup> [GAO-15-257](#).

<sup>8</sup> U.S. Office of Personnel Management, *Introduction to the Position Classification Standards* (Washington, D.C.: August 2009); *Handbook of Operational Groups and Families* (Washington, D.C.: May 2009); and *The Classifier's Handbook* (Washington, D.C.: August 1991).

Resource Management Center (guidance for oversight of test and evaluation infrastructure); (2) Office of the Assistant Secretary of Defense for Research and Engineering (for laboratory policy development and review); and (3) Office of the Assistant Secretary of Defense for Energy, Installations, and Environment (guidance for coordination of DOD real property infrastructure). We also discussed with CBPD officials DOD's draft instruction, *Operations and Management Plan for the CBDP*; and reviewed drafts of DOD's *Chemical and Biological Defense Program Infrastructure Management Functions and Responsibilities* and of a revised DOD Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense Program (CBDP)*.<sup>9</sup> Finally, we met with CBPD officials who had participated in the initial development of plans to implement the roles and responsibilities for infrastructure management. Since DOD has not yet completed its development of the roles and responsibilities, we have not evaluated the effectiveness of DOD's efforts.

We conducted this performance audit from March 2016 to July 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

### **DOD Has Identified an Infrastructure Manager for the Program and Is Implementing a Three-Phased Process to Develop the Roles and Responsibilities**

DOD has identified the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (DASD (CBD)) as the Infrastructure Manager for the CBPD Program. CBPD officials said that DOD also has developed and is implementing a three-phased process led by a working-level integrated product team—scheduled to take place over a 3-year period, ending in 2018—to identify and define the roles and responsibilities for the CBPD Infrastructure Manager.<sup>10</sup> While not complete, the roles and responsibilities defined for the Infrastructure Manager thus far include providing overall coordination, integration, and oversight function for CBPD infrastructure. However, it is too early to evaluate the effectiveness of DOD's efforts to develop and implement the roles and responsibilities of the Infrastructure Manager since DOD's efforts are still in process. The following is a summary of the three phases:

- **Phase one:** Clarifying the Infrastructure Manager's roles and responsibilities regarding the management of *physical* infrastructure.<sup>11</sup>

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<sup>9</sup> DOD Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense Program (CBDP)* (undated draft).

<sup>10</sup> According to CBPD officials, the team decided to use "infrastructure manager" and "infrastructure coordinator" interchangeably in DOD documents because they believed the terms essentially mean the same thing from an oversight perspective. According to CBPD officials, while the CBPD does not actually "own" any of the infrastructure that it oversees, team participants believed that "coordinator" was a more accurate term, although using "manager" emphasizes the position's oversight role.

<sup>11</sup> DOD's CBPD Enterprise defines "physical infrastructure" as laboratories, testing and support facilities, and specialized equipment in those facilities.

- **Phase two:** Implementing the decisions made in phase one; clarifying the Infrastructure Manager’s roles and responsibilities regarding *physical* and *intellectual* infrastructure in relationship with other federal agencies’ respective roles and responsibilities; and developing an infrastructure strategic investment plan.<sup>12</sup>
- **Phase three:** Clarifying the Infrastructure Manager’s roles and responsibilities regarding CBDP *intellectual* infrastructure, specifically its availability to the CBDP.

The Under Secretary of Defense for Acquisition, Technology, and Logistics notified Congress in March 2016 that DOD had identified the DASD (CBD) as the Infrastructure Manager.<sup>13</sup> Officials with the CBDP said that DOD decided to develop the CBDP Infrastructure Manager’s roles and responsibilities in three phases over the course of 3 years, with the work conducted by a working-level integrated product team (herein after referred to as the team) involving participants from across DOD’s chemical and biological defense infrastructure.<sup>14</sup> According to CBDP officials, the team has begun implementing the three phases to develop the roles and responsibilities for the CBDP Infrastructure Manager and also to coordinate those roles and responsibilities with other federal agencies. According to CBDP officials, this team includes broad participation by officials across DOD to prevent the exclusion of important stakeholders and to limit the risk of miscommunication about the team’s work.<sup>15</sup>

### Phase One

In phase one, which the team completed in October 2016, DOD added clarification about the roles and responsibilities regarding the management of physical infrastructure into draft DOD Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense Program (CBDP)*, which was still undergoing legal review as of May 2017. The draft directive delineates, among other things, that the DASD (CBD), as the CBDP Infrastructure Manager, is to conduct overall coordination, integration, and oversight of DOD infrastructure required to perform CBDP-related research, development, test, and evaluation and operational mission support by:

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<sup>12</sup> DOD’s CBDP Enterprise defines “intellectual infrastructure” as the knowledge and skill capabilities of its personnel. Intellectual infrastructure is subject-matter expertise, such as that provided by researchers in bioengineering, systems biology, microbiology, molecular modeling, computational biology/bioinformatics, mechanistic neurobiology, material science for drug delivery systems, inorganic chemistry, gene expression/splicing, biostatistics (experimental design), organic/synthetic chemistry, and structural biology. See [GAO-15-257](#).

<sup>13</sup> Also in this March 2016 letter, the Under Secretary of Defense for Acquisition, Technology, and Logistics stated that the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs would update the DOD directives and instructions related to the roles and responsibilities for managing the CBDP infrastructure by December 31, 2016. As of May 2017, the updates were still in process or under development.

<sup>14</sup> CBDP officials stated that the working-level integrated product team grew out of a “sensing session” on infrastructure issues and was further driven by the congressional mandate in the conference report that accompanied the National Defense Authorization Act for Fiscal Year 2016. According to a Joint Inspector General guide, sensing sessions are group interviews that can serve as sources of information. Their objective is to provide a sense of the perceptions and opinions of the group’s members. See DOD, *Joint Inspector General Inspections Guide* (Apr. 1, 2011).

<sup>15</sup> Participants in the working-level integrated product team include, but are not limited to, officials from the following organizations within DOD: Office of the DASD (CBD); Office of the Assistant Secretary of Defense for Research and Engineering; Office of the Assistant Secretary of Defense for Energy, Installations, and Environment; Office of the Assistant Secretary of the Army for Acquisition, Logistics, and Technology; and Defense Health Affairs. CBDP officials said that there is a separate, concurrent effort looking at the development of infrastructure metrics and analysis.

- coordinating with the Assistant Secretary of Defense for Health Affairs; the DOD Executive Agency for CBDP; the Secretaries of the Military Departments; the Director, Defense Advanced Research Projects Agency; and the Director, Defense Threat Reduction Agency, to plan, program, and budget for DOD CBDP infrastructure and core scientific capabilities, including laboratories and associated safety, security, and control measures;
- establishing procedures to maintain continuous insight regarding inventory of research, development, test, and evaluation infrastructure supporting CBDP; and
- advising the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs throughout the planning, programming, budgeting, and execution processes regarding infrastructure resource requirements to meet mission objectives.<sup>16</sup>

DOD, as a part of phase one, also developed a draft plan entitled, *Chemical and Biological Defense Program Infrastructure Management Functions and Responsibilities*.<sup>17</sup> This infrastructure management guidance, among other things, is designed to facilitate a holistic process to manage infrastructure that supports CBDP. This initial version is limited to guidance on physical infrastructure and does not include guidance concerning the personnel (i.e., intellectual infrastructure) funded to perform research, development, test, and evaluation activities. This draft guidance also outlines the role and associated functions that support the DASD (CBD) as the Infrastructure Manager for the CBDP. To ensure that decisions are well informed and holistic, this guidance includes associated implementation activities needed to facilitate an infrastructure management process and integration within the CBDP Enterprise. In addition, this draft document highlights supporting infrastructure roles, responsibilities, and processes outside of the CBDP Enterprise that enable effective management of CBDP infrastructure that is synchronized with other infrastructure related processes of DOD. This document also will provide the methods by which the overarching DASD (CBD) guidance is met. Future revisions are planned, according to CBDP officials. The next revision, following phase two, they stated, will incorporate an updated description of CBDP infrastructure management processes, including monitoring of applicable interagency, industrial, academic, and international infrastructure. They added that a subsequent revision after phase three will integrate any processes specific to management of CBDP intellectual infrastructure into the document.

According to CBDP officials, to develop the draft directive and plan, the team studied DOD directives and instructions, as well as other DOD guidance, related to similar oversight roles for similar DOD programs, especially those overseen by other assistant secretaries within the Office of the Under Secretary of Defense for Acquisition, Technology and Logistics. They said that the team's intent was to build the roles and responsibilities of the CBDP Infrastructure Manager within the existing sets of DOD structure and guidance rather than to duplicate the efforts of other offices within DOD. CBDP officials said that the team did not look at guidance from outside DOD, nor were they aware of any external guidance that specified how to develop roles and responsibilities for a position like this one. However, DOD officials did consult U.S. Office of Personnel Management guidance regarding the typical roles and responsibilities for a

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<sup>16</sup> DOD Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense Program (CBDP)* (undated draft).

<sup>17</sup> CBDP officials said that this plan will eventually become an annex to the *CBDP Operations and Management Plan*, which is eventually intended to become a DOD instruction.

position DOD created to support the Infrastructure Manager.<sup>18</sup> CBDP officials said that the team proposed an infrastructure support position for an individual at the GS-14 level who would be responsible for taking the day-to-day lead within the department in implementing the CBDP Infrastructure Manager's roles and responsibilities.<sup>19</sup>

## Phase Two

Phase two currently is underway and scheduled for completion by the end of calendar year 2017, according to CBDP officials. First, the CBDP enterprise will implement the roles and responsibilities identified in phase one. Second, the team is in the process of clarifying DOD's interagency roles and responsibilities regarding physical and intellectual infrastructure for chemical and biological defense and plan to finish it on schedule by the end of calendar year 2017. CBDP officials said that they intend to use existing processes, such as interagency mechanisms from the Department of Health and Human Services' Public Health Emergency Medical Countermeasures Enterprise, where possible, and to identify gaps in medical countermeasure coverage rather than introducing anything new based on the CBDP Infrastructure Manager's role.<sup>20</sup> They also stated that phase two will include the alignment of various CBDP processes to provide the information necessary to the CBDP Infrastructure Manager to determine the infrastructure needs of the CBDP, where there are shortfalls, and where there may be excess infrastructure. CBDP officials noted that some of these efforts also address recommendations from GAO's June 2015 report, such as the recommendation to establish timelines and milestones for achieving identified chemical and biological infrastructure goals. These efforts, they stated, include a core competencies review, an infrastructure composition and disposition study, Biosafety Task Force study, and others.<sup>21</sup> This alignment of processes is focused on being able to crosswalk key information, data, and milestones among

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<sup>18</sup> According to CBDP officials, the team consulted the following U.S. Office of Personnel Management guidance in analyzing the position supporting the CBDP Infrastructure Manager: (1) *Handbook of Occupational Groups and Families* (2) *The Classifier's Handbook*, and (3) *Introduction to the Position Classification Standards*.

<sup>19</sup> According to CBDP officials, the description was not submitted to the U.S. Office of Personnel Management for official determination due to the lack of available government billets in the Office of the Secretary of Defense. They said the position was not filled, and is not expected to be filled, as it was originally conceived. To mitigate this situation and ensure continuity, a contract support position was added to the office to work on infrastructure issues in addition to the ongoing individual detailed to the office. Once the current hiring freeze is lifted or an exception to the freeze is granted, they said that the individual in the new government billet will lead the Infrastructure Manager's effort with support from the current individual detailed to the office and the contractor support.

<sup>20</sup> In 2006, the Department of Health and Human Services established the Public Health Emergency Medical Countermeasures Enterprise, a federal interagency body that includes various Department of Health and Human Services agencies and other federal departments, such as DOD, to advise the Secretary of Health and Human Services on medical countermeasure priorities and approaches to the development, acquisition, stockpiling, and distribution of medical countermeasures. It is composed primarily of officials from the Health and Human Services Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Food and Drug Administration, which have specific responsibilities for countermeasure development and acquisition. This organization also includes officials from other federal departments and offices, such as the Departments of Defense, Homeland Security, Veterans Affairs, and Agriculture, and the Executive Office of the President. Prior to the establishment of this organization—from 2004 to 2006—the Executive Office of the President led interagency coordination efforts to establish chemical, biological, radiological, and nuclear medical countermeasure requirements. See GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization*, [GAO-14-442](#) (Washington, D.C.: May 15, 2014).

<sup>21</sup> A Biosafety Task Force assessed the optimal distribution of research, development, and production activities at the laboratories supporting the CBDP.

the CBDP processes so that infrastructure capacity is easier to measure and quantify. Lastly, CBDP officials said that phase two will also include the development of a *CBDP Infrastructure Strategic Investment Plan*—targeted for completion in December 2017 and continually maintained thereafter—designed to guide CBDP infrastructure lifecycle management efforts and inform program investment decisions.

### Phase Three

Phase three—efforts to clarify the CBDP Infrastructure Manager’s roles and responsibilities regarding CBDP intellectual infrastructure—will begin once phase two is completed, according to CBDP officials. CBDP officials said they plan to complete phase three by the end of calendar year 2018. CBDP officials informed us that ensuring the availability of intellectual infrastructure is a commonly identified issue at the CBDP laboratories. They cited the examples of the West Desert Test Center and Biological Test Branch at Dugway Proving Ground, Utah, which have challenges recruiting talent due to their remote location. However, they also noted that the proximity to numerous cutting-edge research facilities in the mid-Atlantic region presents retention challenges to the other laboratories. CBDP officials added that phase three will seek to leverage efforts conducted at the CBDP component level (e.g. Joint Science and Technology Office) and also at the performer level (e.g., laboratories and the West Desert Test Center) to identify, align, and resource appropriate intellectual infrastructure.

As we continue to monitor DOD’s progress in addressing our June 2015 recommendations, we will focus on DOD’s progress in implementing phases two and three.<sup>22</sup>

### **Agency Comments**

We are not making recommendations in this report. DOD reviewed a draft of this report and provided written comments (reproduced in the enclosure). In its written response, DOD confirmed its three-phased approach and said that the schedule remains achievable, with planned completion by the end of calendar year 2018. Further, DOD said that the CBDP Infrastructure Manager continues to coordinate with other federal agencies, such as the Department of Homeland Security, to maximize effectiveness and avoid duplication, specifically as the departments assess the potential impacts of the Fiscal Year 2018 President’s Budget.

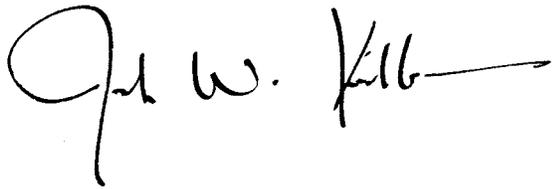
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<sup>22</sup> GAO-15-257.

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We are sending copies of this report to the appropriate congressional committees and the Secretary of Defense. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions concerning this report, please contact Joseph W. Kirschbaum at (202) 512-9971 or [KirschbaumJ@gao.gov](mailto:KirschbaumJ@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report include Mark A. Pross, Assistant Director; Vincent Buquicchio, Michele Fejfar; Ashley Grant; Mae Jones; Clarice Ransom; Bethann E. Ritter Snyder; Sabrina Streagle; and Edwin Yuen.

A handwritten signature in black ink that reads "Joe W. Kirschbaum" with a long horizontal flourish extending to the right.

Joseph W. Kirschbaum  
Director, Defense Capabilities and Management  
Enclosure

*List of Committees*

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**Enclosure: Comments from the Department of Defense**



NUCLEAR, CHEMICAL, AND  
BIOLOGICAL DEFENSE PROGRAMS

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JUN 16 2017

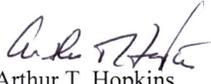
Dear Mr. Kirschbaum:

This is the Department of Defense (DoD) response to the Government Accountability Office (GAO) Draft Report, GAO-17-522R, "Chemical and Biological Defense: DoD Has Identified an Infrastructure Manager and Is Developing the Position's Roles and Responsibilities," dated June 2, 2017 (GAO Code 100701).

The DoD provided GAO with its approach for implementing the Chemical and Biological Defense Program (CBDP) Infrastructure Manager role prior to and during the exit conference for GAO Engagement Code 100701: "Infrastructure Manager for Chemical and Biological Defense Program." The three-phased approach proposes a schedule for updating or developing critical CBDP infrastructure management guidance documents. The schedule currently remains achievable and phase three is planned for completion by the end of Calendar Year 2018.

Additionally, the CBDP Infrastructure Manager continues to coordinate with other federal agencies to maximize effectiveness in related chemical and biological infrastructure and avoid duplication. We are currently coordinating with the Department of Homeland Security (DHS) to assess the potential impacts of the Fiscal Year 2018 President's Budget, which proposed removal of all funding for the DHS's National Biodefense Analysis and Countermeasure Center and Chemical Security Analysis Center. The coordination efforts will inform a unified CBDP evaluation on the gravity of these closures, their potential impact to the CBDP mission, and the cost of any actions to mitigate those impacts.

Sincerely,

  
Arthur T. Hopkins  
Acting

(100701)

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