

# Journal

Defense Standardization Program

January/March 2005

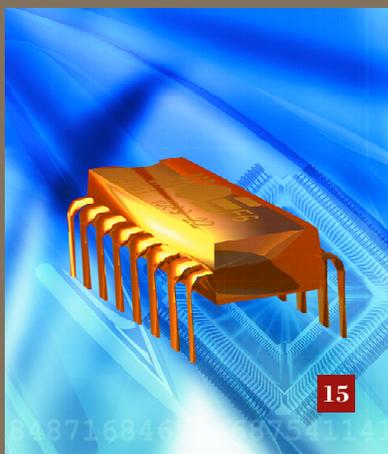
## Defense Labs



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Tomorrow's Avionics Marketplace  
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It was President Harry Truman who said “No aspect of military preparedness is more important than scientific research.” Much has changed in the capabilities of the warfighter since that message to Congress on December 19, 1945, and through it all, our defense laboratories were there.

The history of our defense laboratories can probably be traced back further than the 1940s. I am sure that if you were to make a scholarly guess, you might find that these defense labs probably were born during the industrial revolution when our manufacturing capability converged with the need to equip large national armies. And they matured when the enormous logistics demands of the warfighter during World War I and World War II were paramount.

These labs have had a long history of not only supporting our servicemen and women abroad, but also of ensuring our stance as one of the most effective and lethal fighting forces in the world. For more than 150 years, defense laboratories have been on the forefront of national defense, ensuring that all requirements and capabilities for the warfighter are met. The demands of the warfighter today continue to drive the work being done in the defense laboratories.

So how does standardization fit into the defense labs equation? It's very simple actually. Defense labs are the fabric that binds innovation and standardization together. Defense labs can

## DEFENSE LABORATORIES— CONTRIBUTING TO MILITARY PREPAREDNESS

provide myriad services from research and development to testing certification, recertification, and qualification based on the MilSpecs and MilStds we use.

In one example in the upcoming pages, you will read how a team at the Critical Reagents Program (CRP) developed a formal quality



**Gregory E. Saunders**  
Director, Defense Standardization Program Office





management system in producing and fielding high-quality biological detection assays in support of the warfighter. The military uses products from the CRP to sample, detect, and diagnose diseases caused by pathogenic agents.

It was CRP detection kits that first identified the anthrax powder in Senator Daschle's office on October 15, 2001, and it was CRP detection kits that identified ricin toxin in Senator Frist's mailroom on February 2, 2004. In order to standardize, the CRP established a collaborative process that utilized an Integrated Digital Environment that enabled the best ideas from DoD scientists to be brought forward, shared, and integrated into one joint solution when dealing with the threat of a bio-terrorist attack. Virtual teaming and standardization of processes not only save time and money; they also save lives.

I dedicate this edition of the *Defense Standardization Program Journal* to the men and women in our own defense laboratories. As you can see from the above, and from the articles in this Journal, the contributions being made are not only imperative to national defense, but also to the safety and security of those fighting abroad.

President Truman recognized the value of defense labs—not only in outfitting the warriors of his day, but also in developing the warfighters of tomorrow. Defense labs are an invaluable resource, adding daily to our capabilities with new technologies and applications of technology. I believe that President Truman would be pleased to see the progress made in the defense laboratories. I also believe that he would be pleased with the way the output from the labs is used, documented, and implemented through our standardization program.



# The Next DMS Train Wreck

Premature Wear-Out of Integrated Circuit Components

By Gary Gaugler



The past 5 years have seen monumental changes in how integrated circuits (ICs) are designed and manufactured. The reality for commercial off-the-shelf (COTS) ICs is that new generations emerge as often as every 14 months and sometimes less. Today, as technology embraces the extreme submicron realm, manufacturers are predicting and designing for component lifetimes of 10 years or less for commercial applications. ICs, which in the past had lifetimes that were seemingly infinite, now may exhibit early wear-out or failure. Although this is not a significant problem for commercial applications, it has serious implications for ICs used in military systems and in harsh environmental applications.

Historically, the principle of IC obsolescence was based on the discontinuance of manufacturing processes, referred to as diminishing manufacturing sources (DMS), and the subsequent inability to procure legacy parts, due mostly to economic factors. Today, this sole reason for DMS is itself rather obsolete or at least fundamentally changed in definition. We must now consider the nature of the technology itself and, as an additional factor, component wear-out. This means that IC components should be rigorously and carefully selected during system design and upgrades to ensure acceptable operational lifetimes. Failure to carefully select components will cause premature system failure—especially in a military environment.

Research performed by the Defense Microelectronics Activity (DMEA) in the past year encompasses IC evaluation and procedures with the goal of providing a quantitative and standardized method of predicting the lifetime of COTS ICs when used in non-commercial applications—especially when used in military applications. DMEA has focused its research on electromigration and metal interconnect degradation. Much of that research has involved the

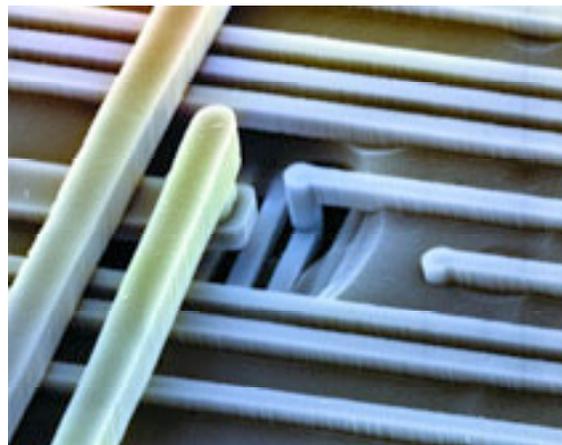
use of electron backscatter diffraction (EBSD) and the scanning electron microscope (SEM). Through EBSD analysis, researchers can measure and quantify the effects of accelerated stressing of interconnects and thus predict IC lifetimes. In its DMS Executive Agent role, DMEA is working to establish a repeatable and standardized approach for evaluating the lifetime of COTS ICs before they are used in fielded systems.

In the past, obsolete or non-procurable ICs were replaced part for part. This worked well, and still does to a limited extent, through the use of the existing stockpiles of aftermarket companies. However, because of advances in IC fabrication technology, hundreds of legacy ICs on a single circuit board can be replaced with one IC component. This is done via transformational technology compression based on modern commercial IC fabrication processes licensed by DMEA for DoD applications. DMEA fabricates and produces the replacement ICs in its DoD foundry at Sacramento, CA. The transformational technology compression replacements use IC fabrication processes that are well defined and certified for long-term DoD applications. These are mature and proven replacement processes. Therefore, the challenge facing DMEA and DoD contractors is how to use today's most modern and unproven IC fabrication methods and how to predict the lifetime of new COTS ICs for the duration of the intended application.

Legacy microcircuits used aluminum metal interconnects and typically were limited to no more than three layers of interconnects. Furthermore, the interlayer dielectric (ILD) was formed by deposition and etch-back methods of silicon

oxides. As IC processing technology advanced and the number of interconnect layers increased, there was a major movement toward the use of copper interconnects and "damascene" construction. Damascene is an ancient method of inlaying gold or silver into steel or other supporting materials. Modern damascene IC manufacturing for feature sizes less than 0.25 micrometer is based primarily on electrodeposition of copper with advanced ILD such as organic ILD and planarization using chemical milling processes rather than traditional deposition and etch-back.

Copper is preferred over traditional aluminum due to copper's lower resistivity and other beneficial factors. This allows ICs to operate at higher frequencies and at greater efficiency than is possible for ICs made with aluminum interconnects. The photo shows a detail of a 180 nanometer copper IC's interconnects when exposed via chemical etching.



**Detail of Interconnects on 180 nm Copper IC.**

A big problem with copper interconnects is stopping copper ion migration and electromigration. This is the slow but inexorable process of copper ions migrating out of the interconnect metal and into the surrounding ILD. As in-

terconnect-to-interconnect spacing becomes ever smaller, the probability of electromigration between one interconnect and another dramatically increases. Thus, the commercial goals of higher performance, smaller size, and lower cost affect IC component reliability and lifetime for military applications.

Using EBSD as a key analysis technique, researchers can describe copper interconnects based on grain size, grain size distribution, and crystal lattice orientation (or misorientation) and can measure how any or all of these change under environmental stress. Recent research has shown that copper grain size tends to converge to the width of the copper interconnect.<sup>1</sup> Extending this insight via accelerated aging of COTS ICs can reveal inherent weaknesses in COTS ICs, which indicates that they should not be used in military applications.

Early generations of ICs have large grain structures and can exhibit many types of interconnect defects. The accompanying photo shows etching defects on the mid right side and a metal void in the mid left side.



#### **Etching Defects.**

Early-generation ICs with such defects would pass full functional testing. Subsequent testing

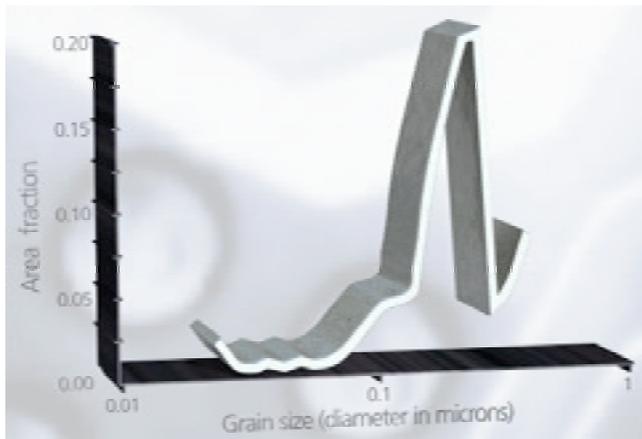
after static burn-in would also not reveal any significant functional failures. However, such ICs would be failed for military applications when evaluated according to QD requirements of MIL-PRF-38535.<sup>2</sup>

Although the standard failure analysis techniques work well for legacy ICs, they are not at all satisfactory for state-of-the-art ICs. Hence, DMEA's work with EBSD and COTS reliability prediction marks a critical juncture in how COTS ICs are to be selected and graded for military environments.

The total analysis of COTS ICs includes evaluation of the interconnect metal and ILD integrity. SEM EBSD serves for analyzing metal interconnects, while traditional cross-sectioning provides insight into the ILD. All of these analytical phases can be augmented by energy dispersive x-ray analysis or Auger surface analysis microscopy.

As noted earlier in this article, a fundamental basis for analyzing COTS ICs and predicting their potential lifetimes is interconnect grain statistics. Grain crystal lattice orientation and structure are very much indicative of overall IC reliability. Grain size distribution (shown in Figure 1) can be used to a great extent to determine long-term effects of environmental exposure and power-on/power-off stress cycling.

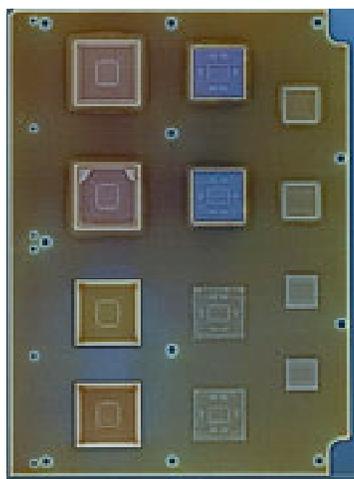
Recent generations of microchips also introduce difficulties associated with their packaging technology. Some ICs are plastic encapsulated, while others are of the flip-chip design. Gone are the days when almost any IC could be procured in a hermetic package for military use. Today, the commercial marketplace drives the



**FIGURE 1. G** grain Size Distribution.

semiconductor industry. Consequently, besides dealing with component wear-out as a component selection criterion, DMEA is analyzing how best to select ICs and conformal coatings relative to resistance to moisture intrusion and corrosion.

Analyzing resistance to moisture intrusion and corrosion is done by environmentally stressing packaged ICs mounted on test circuit boards.



The boards and ICs are heated, pressurized, and soaked in water in a special pressure chamber. After stressing, each board is analyzed for corrosion using neutron radiography. Neutron radiography is ideal for this type of analysis because the hydrogen atoms trap neutrons. Hydrogen is the key element associated with active corrosion

and moisture intrusion. On a neutron radiograph, corrosion areas and those with moisture appear as a light shade, whereas other areas that have allowed neutrons to pass through are darker.

In total, new generations of microcircuits have many advantages but also a disparate mix of inherent and subtle disadvantages. With a historical background of past IC technologies, and a clear view of present and future IC technologies and sustainment, DMEA is working to keep DoD systems operational and supportable indefinitely into the future. For such a dynamic technological environment, this is truly a “moving target.” As a federal laboratory deeply involved in advanced development, DMEA is also keenly intent on operational needs and requirements. This is a unique combination of research, development, testing, engineering, and system sustainment under one umbrella.

<sup>1</sup>D. Field, J. Muppidi, and J. Sanchez, “Electron Backscatter Diffraction Characterization of Inlaid Cu Lines for Interconnect Applications,” *Scanning*, 25, 2003, pp. 309–315.

<sup>2</sup>QD is the wafer back-qualification procedure as described in MIL-PRF-38535. The procedure allows unqualified wafer lots to be qualified for MilSpec as QD when certification for the qualified manufacturers list is not possible. This then allows military parts to be provided from old runs.

#### About the Author

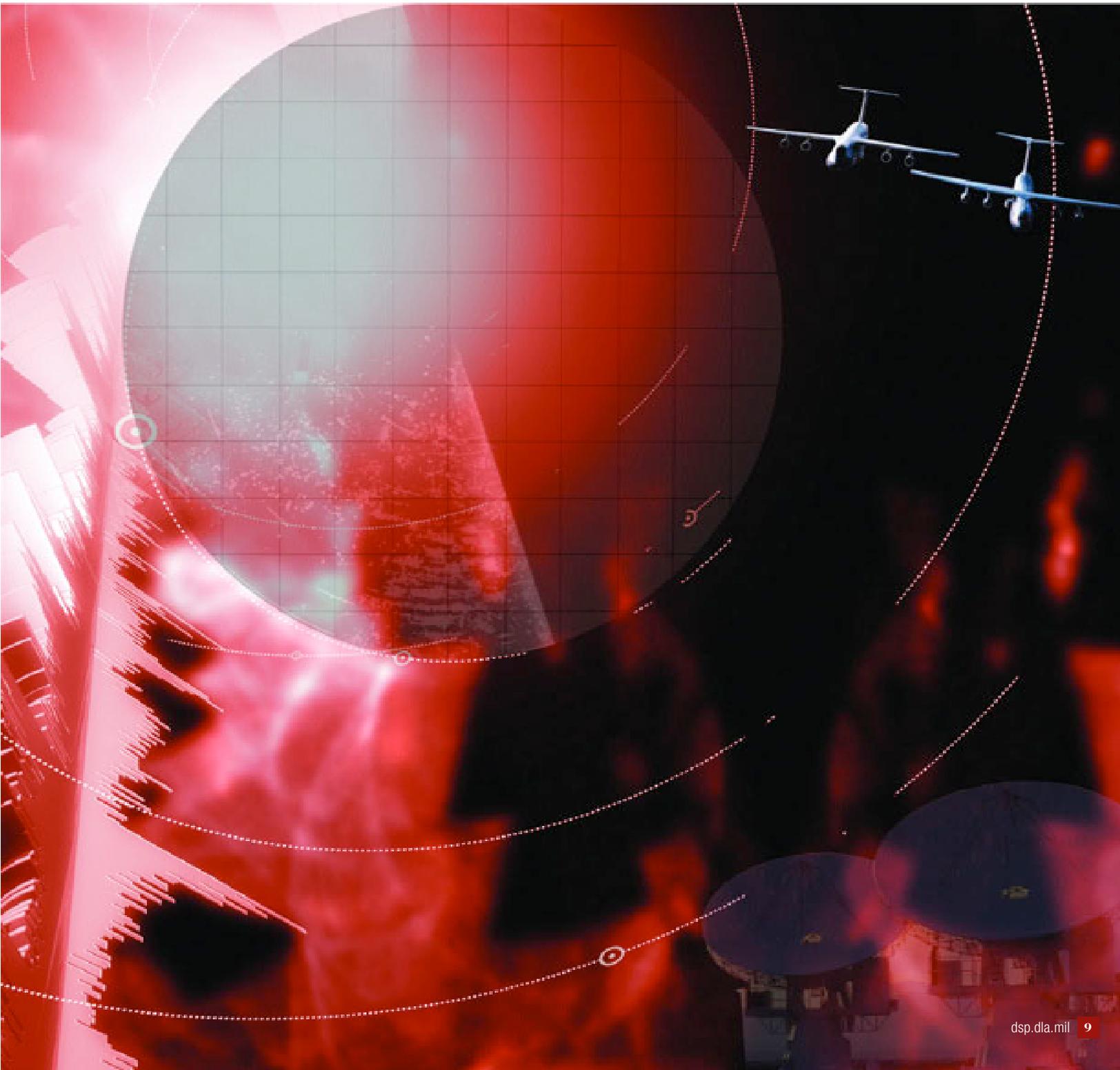
Dr. Gaugler, a technical advisor to the Defense Microelectronics Activity, has been working in the microelectronics field for more than 30 years. His current interests are IC design, process development, simulation, modeling, and SEM analysis of ICs. He has received the Secretary of Defense Productivity Excellence Award, the Air Force Exemplary Civilian Service Award, and the Air Force Meritorious Civilian Service Award.✱



# Tomorrow's Avionics Marketplace

## A New Way for the Aviation Community to Shop

By Dan Slick



## Introduction

The Aviation Engineering Board—a DoD, industry, government, and academia effort sponsored by the Joint Aeronautical Commanders Group—has taken the lead as an agent for change in the aviation community. One of board's exciting new projects is an interoperability initiative called the Modular Open Systems Approach (MOSA). MOSA offers solutions to the many challenges associated with maintaining and modernizing avionics systems.

An ambitious and necessary DoD goal is to reduce total ownership costs (the costs to buy, use, and maintain aviation and weapon systems) of its aircraft and to allow for much greater technology refresh. A study of the flying program in the Navy revealed an annual 5.7 percent cost increase to maintain its aging fleet of aircraft. The focus of MOSA is to take that first necessary step in reducing costs, with respect to both hardware and software. How? By establishing an industry-accepted, true open systems approach in which common data protocols, interfaces, and processes are used.

MOSA is placing design and manufacturing companies at the forefront of a government and industry collaboration, which is being termed by those close to the initiative as “effects-based partnering.” Industry is being empowered to do what they do best: design the right technology to meet our aviation needs. Government agencies are also a part of this unique partnering by guiding and supporting the development of new, better avionics systems that meet today's and tomorrow's missions. The result will be an environment in which systems become less expensive, technology is refreshed quickly, and dissimilar components are replaced with standardized ones capable of being used on aircraft with similar operating requirements.

## Business in Today's Marketplace

If you consider for a moment how the computer industry has structured its business approach, it's no wonder that computers have become a common household item. Not only have many hardware features become less and less expensive each year—thanks mostly to an open marketplace where users have many buying options across a wide variety of companies—but the technology has been designed to allow the technology to be refreshed to meet changing computing needs and to offset obsolete components.

However, the way DoD defines, buys, and maintains its own aircraft-related electronics can be found on the opposite end of the pendulum swing. Meeting mission requirements for its avionics systems is the result of many years of budgeting, requirements definition, complicated and time-consuming contracting procedures, a slow development and implementation schedule, and a sustainment program that would bankrupt most healthy companies. To compound the problem, the procurement process ensures that by the time a system makes its way into an aircraft, the system is at least 7 years out of date technologically. The complexity of the current acquisition method is illustrated in Figure 1.

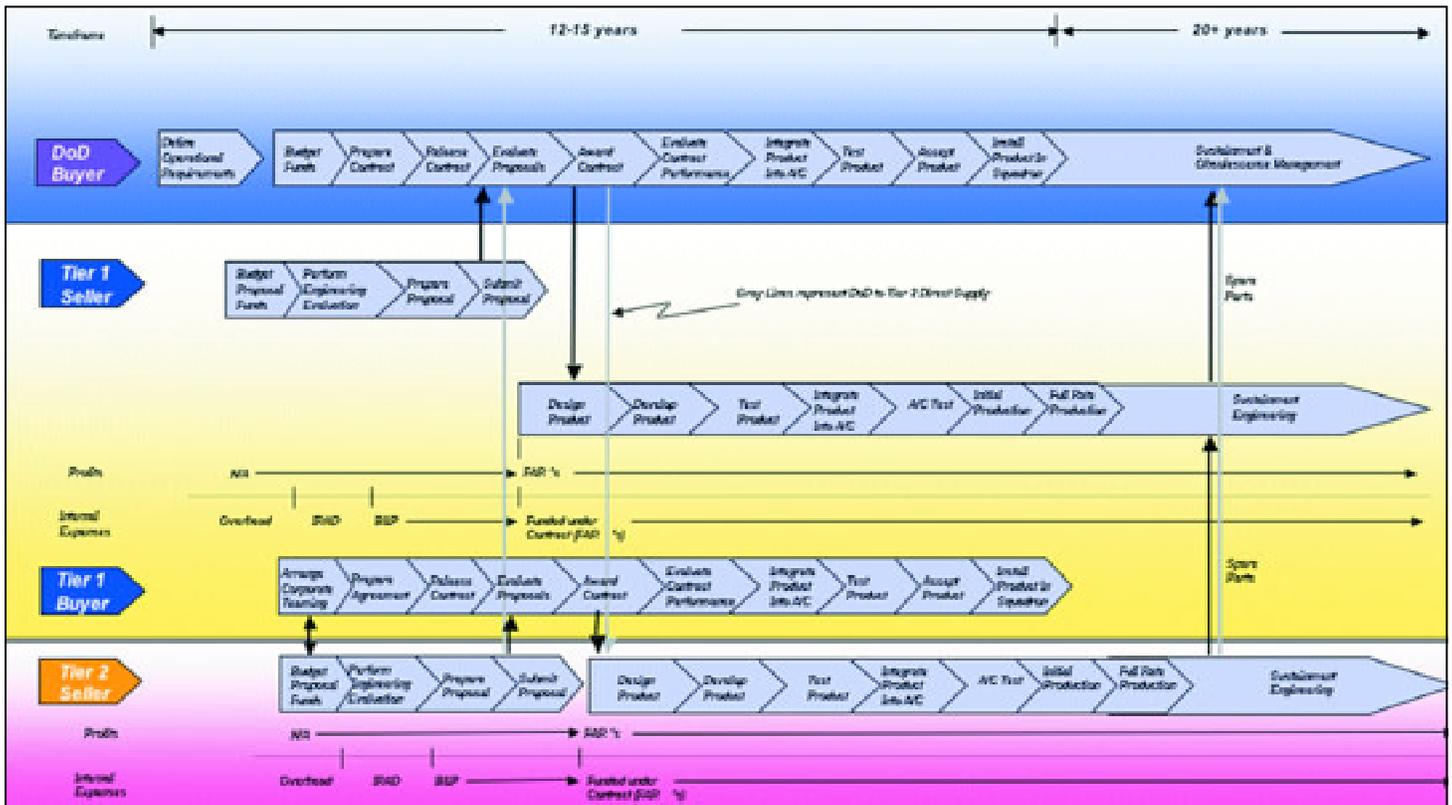


FIGURE 1. Share Market Model.

Although the intuitive answer to correcting what’s broken with DoD might seem to be for avionics vendors to adopt a business model like that used by the computer industry, it’s not that easy. First, DoD is a demanding customer, with some stringent design specifications and unique operating requirements. These stringent requirements force many companies into investing significant amounts of money, time, and talent to develop suitable systems. Second, along with the awarding of contracts to develop these systems naturally comes the follow-on support to upgrade them. Therein lies perhaps the largest impediment to change (besides DoD’s cumbersome procurement procedures): industry has a vested interest in supporting what it has already developed. There is little risk and cost for industry to hold on to the segment of the market they now control. An open market where newer systems or improved components could be purchased from a variety of companies would eliminate the substantial earnings now tied to sustainment contracts. The bottom line: industry has very little financial incentive to change.

Today, much of the operating and support costs of avionics systems can be attributed to a lack of standardization and modernization. Many challenges need to be met:

- *One strategy.* Many avionics systems are unique to certain aircraft, because each employs its own proprietary “open systems” approach. As a result, maintenance, component inventories, and upgrades prove especially costly without an economy-of-scale purchasing strategy.

- *Funding.* A limited amount of funding exists for aircraft operations and support. More dollars spent fixing old technology means less money to insert new technology.
- *Procurement.* It typically takes between 8 and 15 years to plan, develop, test, and install an avionics upgrade. Because technology undergoes significant advancement every 3 1/2 years, obsolescence keeps avionics systems well behind the technology curve.
- *Economy of scale.* With the vast number of different avionics systems and components used in aircraft, it is impossible to realize an economy of scale, where more similar parts can be produced for less cost.
- *Diminishing manufacturing sources.* Diminishing manufacturing sources have resulted from constant technology updates. Companies simply do not support dated hardware and software. As technology advances ever faster past our aging systems, the ultra-expensive aftermarket suppliers of components control an ever-increasing percentage of our sustainment budget, prohibiting new procurement.
- *Aging.* As components are kept in the inventory longer, the failure rate will continue to increase. As the density of components increases, the wear-out rate is now measured in years rather than decades. "Using up" an electronic device is now possible.

### **Business in the MOSA Marketplace**

A marketplace needs to be established where there are no lengthy contracts, innovation is rewarded, industry standards are applied across all avionics systems, risks are accompanied by the potential for huge gains, and DoD's requirements are driven by road maps and surveys that pinpoint short- and long-term needs.

The first step toward change is to develop a business case for MOSA. Despite the obvious merit of a consolidated approach by industry and government to field more affordable and modern avionics systems, the effort still needs to be defined and qualified. The business model that will be developed by MOSA's industry/DoD partnership will define the changes needed in procurement at the DoD level and in development at the industry level. How can the procurement process be simplified? How will industry generate profit in an open-market scenario? Who will establish design standards? These and many other questions will be addressed in the business model and the ensuing marketplace analysis.

Business models from other companies, academic and economics experts, and a host of other resources will be relied upon to develop and validate the MOSA business model. Plans include developing case studies on selected avionics suites to test this new business approach. Great importance will be placed on ensuring that whatever final business model is developed will best serve the needs of the government, in regard to both capabilities and cost. Equally important, the model will clearly define how and how well the industry will make a profit under this new way of doing business with the government.

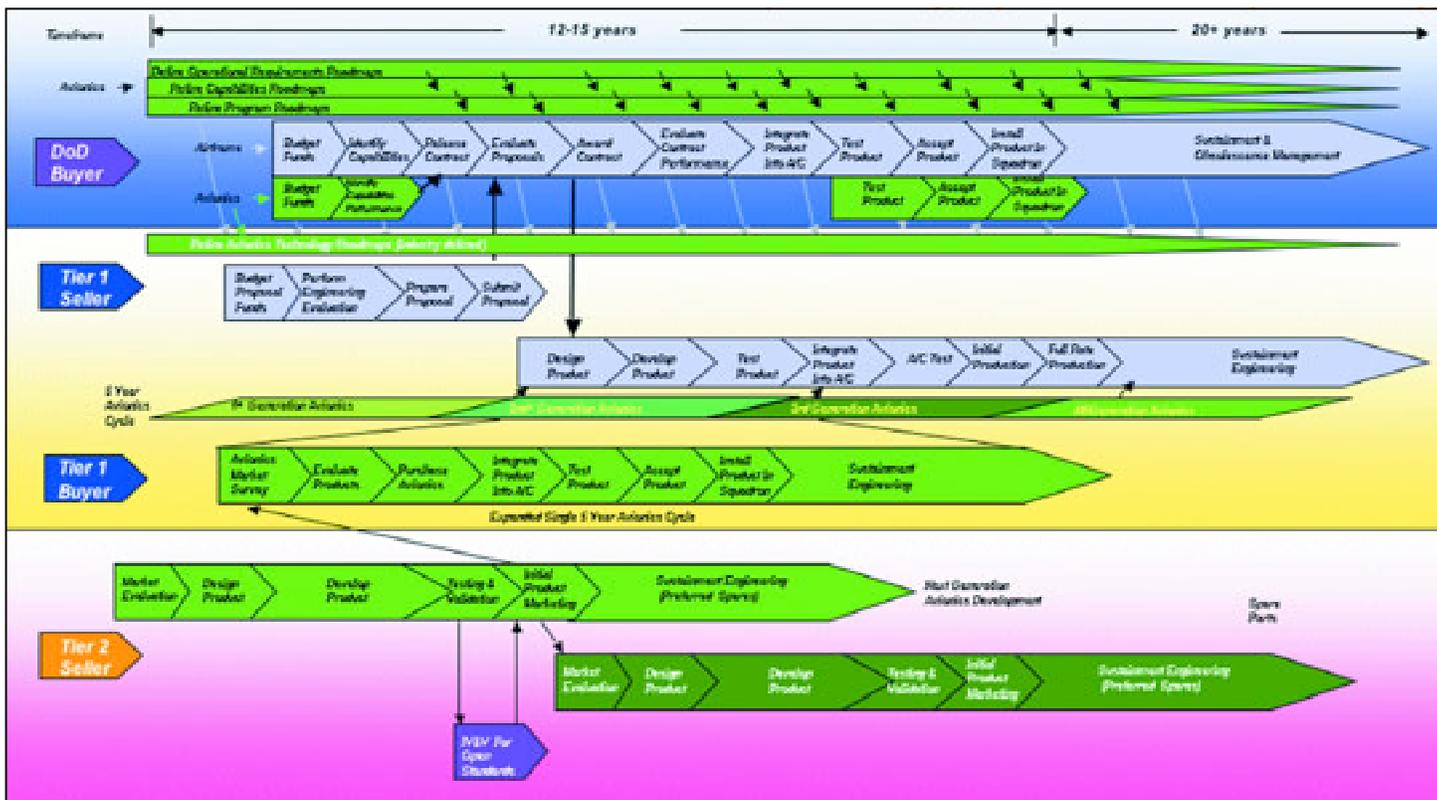


FIGURE 2. ShareMarket Model (Airframe Buy); Open Market Model (Avionics Buy).

A MOSA marketplace will be designed to streamline how DoD fields new avionics systems. Preliminary procurement steps that have been envisioned include the government identifying its needs, relaying these needs to industry, establishing a date when this new technology will be needed, allowing industry time to develop and test their products, buying the best systems made available, and then repeating the process every 3 to 5 years to keep pace with technology (see Figure 2).

### Looking Ahead

Reduced budgets and the need to operate much more efficiently are forcing DoD to consider more efficient ways to support their aircraft. The days of individual solutions to common requirements are quickly fading away out of necessity, and the only viable solution to keeping pace with avionics systems modernization is through a collaborative teaming between industry and government agencies.

The MOSA marketplace will be an authentic open systems approach to developing and fielding avionics systems. The following are among the benefits:

- *Open design.* A standard approach to modular open systems architecture will be developed. The standard will allow for manufacturers' avionics systems to have a universal fit and for individual components within systems to be manufactured by many vendors.
- *Affordability.* Through economy of scale, each system and its components will become increasingly more affordable.

- *Modernization.* Common hardware and software will guarantee rapid insertion of the latest technology by eliminating the need for custom-fitted solutions. Because new technology will be implemented at a much faster rate, replacing older equipment more frequently, it is theoretically possible that equipment will be able to operate failure free throughout its life cycle. Dollars spent repairing and maintaining systems will go to procurement of new technology.
- *Common software.* Common computer processes will eliminate the need to constantly rewrite software to meet changing equipment capabilities and demands.
- *Reduced logistics footprint.* Similar systems and components will result in less equipment in inventory, fewer hours managing that inventory, and less specialization by maintenance personnel repairing dissimilar components.
- *Standardized protocols and interfaces.* The way information is transferred and the means by which it is delivered will become standardized. Besides allowing true interoperability, the common interfaces will also reduce the need for unique fixes for a wide variety of cables, wires, and so on.
- *Partnerships with standards bodies.* Interoperability will help provide a more focused direction for standards bodies, such as the National Defense Industry Association, Aerospace Vehicles Systems Institute, Society of Automotive Engineers, and Institute of Electrical and Electronics Engineers.
- *Road maps.* Agencies will be able to effectively develop technology road maps that identify new systems needed for the future. Less time required to insert new technology will make accurate planning possible.
- *Reparability.* Maintenance personnel will spend more time inserting new technology, rather than constantly fixing old equipment.
- *Scalability.* Commonality will allow components to be added and subtracted without impacting other components in an avionics system.
- *Portability.* Uniform technology will make it possible for the same avionics systems or individual components to be used in aircraft in different branches of the service and even in commercial aircraft.

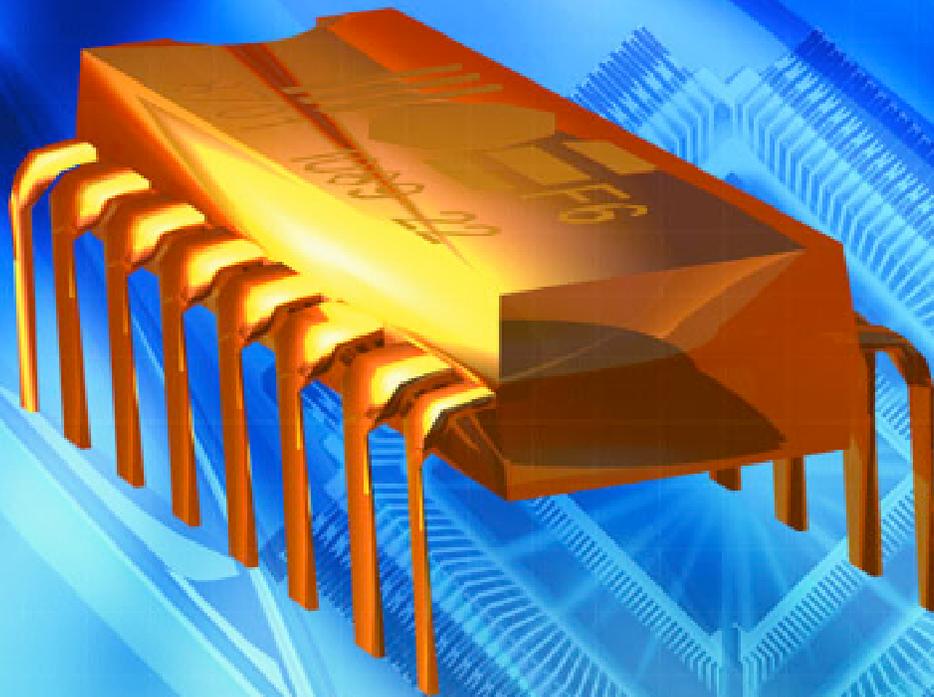
In sum, reduced budgets and the need to operate much more efficiently are causing program managers to consider better ways to support their aircraft. The days of individual solutions to a common challenge are quickly fading away out of necessity, and the only viable solution to keeping pace with avionics systems modernization is through collaborative teaming of industry and government agencies.

### About the Author

Dan Slick is the battlespace system architect within the Naval Air Systems Command's Battlespace Systems Engineering Program. He coordinates open systems initiatives and DoD architecture products to counter the effects of aging aircraft and to ensure systems interoperability within naval aviation and with the Army, Air Force, and NASA. Mr. Slick also cochairs the NATO Avionics Standardization Panel. ✨

# A Virtual Lab Combats DoD's Biggest Obsolescence Problem

By David Robinson



Microcircuit obsolescence is one of our most significant challenges in supporting weapons systems. It is responsible for costly system redesigns and decreased system readiness. To address that challenge, the Defense Logistics Agency (DLA) and the Sarnoff Corporation of Princeton, NJ, undertook the Generalized Emulation of Microcircuits (GEM) program—an innovative combination of government-sponsored technology development with existing private industry production capacity.

Each year, the Defense Supply Center Columbus (DSCC) receives notification of the impending discontinuance of thousands of microcircuit part types. In its role as inventory control point for the microcircuit stock class (Federal Supply Class 5962), DSCC evaluates the supply impact on thousands of microcircuit national stock numbers (NSNs). This startling number of discontinuances comes from an industry whose profit-making opportunities lie in highly competitive and innovative markets like cell phones, home computing, and home entertainment. The demands of those markets for rapid technology turnover, combined with a defense industry market share estimated to be less than 1 percent, have led to the

shutdown of the manufacturing capability that produces many of the microcircuit spare parts we need to support our systems.

Recognizing those industry trends, DoD, in the mid 1980s, began efforts to develop a cost-effective approach to supporting the weapon systems that would continue to be affected by microcircuit obsolescence into the foreseeable future. It was decided that in many cases, the best way to support a weapon system is at the component level—the individual piece-part. The technical approach that was decided upon was to use current technology to create microcircuits that are form, fit, and function equivalents—in other words, emulations—of the obsolete or non-procurable microcircuits. DLA was selected to head the effort due to its applicability to all the services as well as other federal organizations (such as the Federal Aviation Administration and NASA) and DSCC's role as inventory control point for microcircuits.

One very important criterion was that the desired support approach would not itself become obsolete due to the market forces that caused the problem in the first place. Through market research and competitively

awarded exploratory contracts, DLA selected an approach put forward by Sarnoff. Sarnoff can trace its lineage back to RCA Laboratories, which originally developed microcircuit technologies for industry in the 1960s and 1970s. Sarnoff maintains a small microcircuit manufacturing capability used primarily to build custom microcircuits for specialized applications and to prototype parts that are then transitioned to high-volume microcircuit manufacturers for full-scale production. As such, Sarnoff is not subject to the same market forces that originally drove the parts out of production, and it is accustomed to the small production quantities needed to satisfy military microcircuit spare parts requirements.

Sarnoff proposed using one current technology to emulate parts built using 10 or more older technologies. In other words, Sarnoff proposed a “generalized” approach to achieving microcircuit performance rather than an individual and costly approach to recreating the original processes in hopes of duplicating performance. The parts would be built using Sarnoff's microcircuit fabrication facility. The assembly and the performance and quality assurance testing of the finished goods would be subcon-

### Form, Fit, and Function

An item may have many characteristics that could be considered part of its form, fit, and function. The Federal Acquisition Regulation describes form, fit, and function as physical and functional interchangeability. The specification writer's task is to include all of the item's characteristics that are essential to its intended use without including any that would increase cost or reduce competition. In essence, the job of the specification writer is to make sure the specification's users get exactly what they need, without paying for anything they don't. The specification's requirements then define the form, fit, and function of the item represented by its PIN.

tracted to private industry where that capability is readily available and competitively priced. DLA's contribution would be limited to funding the development of the GEM technology, which would be matched to Sarnoff's existing production capability and be flexible enough to be taken to a second or alternate source if the need arose.

From 1987 to 1997, the GEM program transitioned from initial research and development through validation and verification and on to limited production. Sarnoff and DLA demonstrated the technical feasibility of the GEM program by emulating dozens of microcircuit parts types and successfully testing them in multiple military applications. This established the soundness of the GEM approach and proved that GEM parts are compatible with the technology of existing weapon systems. In 1997, GEM achieved full-scale production status, and program management responsibility was transitioned to DSCC.

Using one current sustainable technology to emulate about a dozen older technologies multiplies the effectiveness of limited funds. Another key element to the success and impact of the program is the high degree of commonality and standardization within Federal Supply Class 5962. The GEM program focuses on the digital logic microcircuits introduced in the 1970s and 1980s. Those parts were largely assigned standard JEDEC designations by their manufacturers and were the common building blocks for digital logic design in those decades. (JEDEC, formally known as the Joint Electron Device Engineering Coun-

cil, is the semiconductor engineering standardization body of the Electronics Industry Association, a trade association that represents all areas of the electronics industry.)

The inherent commonality within the microcircuit stock class, combined with an extraordinary standardization effort under MIL-M-38510 and the Standard Microcircuit Drawing Program, resulted in multiple weapon system users being concentrated in a small number of NSNs. The average NSN supported by GEM has over a dozen registered users, and one NSN has more than 90. Solving 90 spare parts availability problems with one solution is very cost-effective.

For GEM to be truly effective, GEM parts would have to be as transparent to the supply system as they are to the intended applications. To do this, GEM parts would have to be supplied to existing NSNs, to existing part numbers, to existing requirements. A major requirement for being able to do that is to meet the requirements of MIL-STD-883 and MIL-PRF-38535. These two documents form the basis for the reliability, quality assurance, and testing requirements for all military microcircuit specifications and for most defense contractor microcircuit part drawings.

In 1996, Sarnoff received final approval for design, fabrication, and device testing in accordance with provisions for transitional certification and qualification to MIL-PRF-38535. This enabled Sarnoff to satisfy 100 percent of the requirements of all the military specifications within its design capability. This gave DoD and de-

fense contractors access to hundreds of part types that had previously become obsolete without any need to change parts lists, technical manuals, part drawings, or part numbers.

GEM parts have met the requirements of more than 100 NSNs that support hundreds of weapon systems; nearly everything in the inventory that flies, floats, or rolls is supported by GEM parts. Without GEM support, these weapons systems would experience decreased readiness, costly system redesigns, and in extreme cases, possible retirement. GEM's cost benefit through the avoidance of system redesign has been conservatively estimated at over \$100 million.<sup>1</sup>

<sup>1</sup>For more information on GEM, please visit [www.gemes.com](http://www.gemes.com).

### About the Author

David Robinson is a supervisory logistics support analyst in DSCC's Commodities Corporate Unit. He is the program manager for DLA's Generalized Emulation of Microcircuits, Shared Data Warehouse, and DMSMS Center of Capabilities programs. Mr. Robinson is responsible for the operations of the DMS office, including coordination of DMSMS LOT buys, DMS policy, and long-term logistics support and engineering assistance to DoD weapons system program offices. ✨

# Standardization in Biodefense Laboratories



## How an Integrated Digital Environment Can Help with Standardization Efforts

By Peter Emanuel, Michael Mazza, and Karen Poffenberger

## **Background**

The Critical Reagents Program (CRP) is responsible for producing, optimizing, and standardizing the use of biowarfare detection and diagnostic test kits used by the U.S. military. Each year, the program produces millions of detection and sampling kits, which are shipped throughout the world, wherever our forces are deployed. CRP assays are inside every major biological defense system fielded by the U.S. military. It was CRP detection kits that first identified the anthrax powder in Senator Daschle's office on October 15, 2001, and it was CRP detection kits that identified ricin toxin in Senator Frist's mailroom on February 2, 2004.

To accomplish its mission, the CRP has established a network of conformance test labs, secure repositories, commercial manufacturing sites, and developmental test centers that act in concert to develop, test, and field the highest quality biological detection assays for the nation.

Since September 11, 2001, the CRP experienced an unprecedented surge in production and in the introduction of new technologies to combat the rising threat of bioterrorism. The deployment of troops to Afghanistan and the invasion of Iraq significantly strained the ability of the program to continue to supply the warfighter with detection capability. As customer requirements increased, it became more difficult to track and manage product inventory, upgrade existing product lines, and manage the influx of new technology. To further complicate issues, the CRP technical sites are separated by distance, which creates a huge challenge in gathering real-time data and coordinating research efforts at each site. In short, the more sales increased, the worse the problem became. The CRP's solution was threefold: reorganize to operate like a commercial firm, take advantage of the Integrated Digital Environment (IDE) to communicate more effectively, and standardize documentation to facilitate the exchange of data and allow for more effective transition of technology.

## **Reorganization**

The CRP was reorganized into six commodity areas corresponding to the program's major product lines. Each area has a commodity manager with clear roles and responsibilities that allow them to focus on a single product and be more responsive to the technical environment. Government scientists who serve as technical advisors support the commodity managers and chair specialized integrated product teams (IPTs) empowered to work through issues.

The combination of high quality and standardization was established as a distinct commodity that touches all products, and a formal quality management system (QMS) was established to integrate quality and standardization processes across the program.

## **Integrated Digital Environment**

The CRP's command structure employed an IDE to facilitate communication among multiple command sites separated by distance and to allow for more efficient virtual teaming. The CRP engaged a software engineer to create a modified CRP IDE web portal that would facilitate the work of the IPTs. The portal can be accessed from anywhere in the world and allows for restricted entry to a collaborative "worktable" where documents can be securely shared and ed-

ited more effectively by multiple users. The portal also serves as a configuration management tool to prevent loss of information or overwriting of the same document. The CRP changed its standard operating procedures and quality documents to create audit trails that show who made what changes and when they were made.

The CRP IDE website has proven to be very useful when hosting standardization IPT meetings via teleconferencing or video teleconferencing. IPT members log into areas created specifically for each meeting where an agenda and all related documents are posted 1 week before the meeting. Tasks assigned during the meeting are then entered into the task management system that records the responsible individuals. If a task is pending or overdue, the system will alert users by sending e-mail messages, and it gives senior leadership real-time visibility into high-priority tasks.

Within the IDE, user groups were created, allowing CRP customers and IPT members to post questions and answers to create a technical chat room. The discussion threads are archived, effectively documenting the process and allowing other users insight into issues at other sites.

Finally, an Automated Inventory Tracking System (AITS) was created to provide real-time status on all CRP products. A catalog was published that assigns each product a specific number. Customers place their orders against specific catalog numbers, an action that officially logs their orders into the system. This gives the CRP and its customers better visibility of inventory and order status and provides a tracking mechanism for the quality documentation associated with each product. When inventory is shipped from a regional repository, the action—and the specific quality documentation (packing slip)—is logged into the IDE. Customers receive an e-mail informing them of the details of their shipment. When customers receive their shipment, they log it into the IDE to close the loop and report on any discrepancies in the shipment. The regional repository receives this

notification automatically by e-mail, thus streamlining the process.

### **Standardized Documents**

The lack of a standardized format for exchanging information and data posed a dilemma for the CRP. Each lab presented test data on their assays in a different format and tested against different panels of threat agents. The CRP had no way to compare the performance of one assay versus another without conducting further costly testing for each potential assay candidate. It became clear that each of the DoD labs must conduct research and development testing in a standardized way using standardized sets of cells or toxins. If the sites could agree on a way to document the test data in the same manner, then it would be possible to directly compare assays developed at any site and make the appropriate recommendations for mass production.

Because the CRP is responsible for transitioning new detection assays developed by multiple supporting sites, the program requires standardized documentation across all the sites in order to facilitate the exchange of data and allow for more effective transition of technology. To address this need, a Defense Technology Objective, sponsored by the Defense Threat Reduction Agency (DTRA), was initiated with the aim of standardizing how test data are documented and portrayed for all molecular- and immunological-based assays for biowarfare detection and diagnosis across all DoD research and development labs. An assay-standardization IPT was assembled to compare how each site created data panels, assess assay performance, and evaluate what the medical and food industry standards programs consider appropriate documentation formats. The result was a single format that is now being used at all Army, Navy, and Air Force development labs.

The assay-standardization IPT challenged the CRP to create standard panels of threat agent cell lines that were common among all sites, had pure lineages, and were confirmed and maintained under the most rigorous standards. To meet this

challenge, the CRP turned to the U.S. Army Medical Research Institute for Infectious Disease, which is the curator of a cryorepository housing a standardized collection of threat agents. Microbiologists and virologists met to discuss how to best create panels and approved the final selection of a geographically diverse collection that reflects the latest genetic lineage research and the current threat assessments of DoD. The DoD Unified Culture Collection (UCC) program developed a system to place identical collections at each primary DoD development site as well as rotating cells such that the integrity of the lines would not be compromised. By working with other DoD labs, many of which had extensive collections of their own, the UCC program has been able to expand its diversity and usefulness beyond what any single site was able to achieve before the program was initiated.

Standardized sets of cells are crucial to support the two specialized repositories that the CRP maintains for the production of gold standard reference materials. The test and evaluation community regularly consumes CRP preparations of threat agents such as *Bacillus anthracis* spores or the DNA from *Bacillus anthracis* in operational tests and training programs. Detection systems are evaluated against preparations of these threat agent reference materials. Failure to meet certain predefined performance objectives in these tests will mean that milestones are not attained. In the case of biological defense systems, the successful completion of these tests is contingent upon their ability to detect batches of prepared biothreat agent reference material. With the UCC program distributing standardized sets of cells, these sites can now produce reference materials derived from the same standardized cell collection used by every DoD development lab. Furthermore, basic research programs can now purchase affordable standardized reference material panels to help them develop new technologies.

Standardized methods of production and quality analysis were created such that each agent has a

step-by-step production and downstream analysis process written in a standardized format. By establishing detailed standard operating procedures and quality analysis processes, it was possible to reproducibly manufacture these reference materials with minimal variation. Today, every CRP repository, commercial production site, and conformance test lab uses a consistent format to document their processes. All documents are linked to an overarching QMS. All certificates of analysis, test results, contracts, and product information sheets are posted on the IDE and can be immediately retrieved by personnel involved in the program.

### **Status**

Because of the events of 9/11 and the current terrorist threat, it is critical that CRP delivers the best possible products as quickly as possible in order to save lives by initiating immediate and appropriate actions in the event of a suspected bio-terrorist attack. Through a formal QMS that focuses on process and product improvements, the CRP can leverage the best possible resources and ensure timely delivery of the best possible products. With the utilization of the IDE as the CRP integration tool to streamline, improve business processes, and save money, more scientists are able to log on from across the country and easily provide their input on improving CRP products. The tool makes it possible to bring forward, share, and integrate, into one joint solution, the best ideas of DoD's scientists without them having to be in the same room. The AITS gives the CRP and its customers a real-time snapshot on the status of their products. It gives the program office the opportunity to better forecast customer requirements and to manage inventory in a way that focuses on the cost savings concept of just-in-time logistics. Virtual teaming and resource consolidation save time and money by allowing the program to draw support from sites anywhere in the nation.

Today, the CRP can offer reference materials derived from a standard set of cells agreed upon by the Army, Navy, and Air Force. Newly developed assays are documented in the same manner and

subjected to testing with material drawn from the CRP reference material program. Research programs sponsored by the Department of Homeland Security (DHS) and the National Institutes of Health are now consuming CRP reference materials. Documentation and processes developed under this program have been posted into a DHS chemical and biological standards assessment, which will drive the development of new standards in this area following a gaps analysis to identify where national standards are needed. Lessons learned from these efforts are being presented to other groups such as the U.S. Department of Agriculture's Animal and Plant Health Inspection Service as it embarks on a related effort to form the Plant and Animal Diagnostic Laboratory Program.

The CRP is currently utilizing the IDE for automated inventory tracking, online issues management, IPT meetings, and document reviews. The CRP is continuing to improve its processes using the current IDE system to gather management metrics such as ordering, shipping, and inventory status. In addition, the CRP will share these collaboration efforts with other federal agencies and with industry and academia. Future efforts will focus on expanding the number of agents that have standard production and analysis documents such that CRP will be able to offer a greater variety of reference materials.

The CRP and DTRA recently engaged the National Institute of Standards and Technology (NIST) to assess and improve the quality program and potentially offer CRP reference materials for sale through the internationally recognized NIST

standards program. Discussions with the United Kingdom and Canada have indicated that their scientists are interested in gaining access to these agents for their testing programs. DoD has made a significant investment to create a gold standard reference material program and can offer a competitively priced product through economy of scale. No single lab could accomplish the production and supply of a quality-controlled and consistent biothreat reference material. The CRP acts collectively to reduce the price of products by offering them to a wide range of consumers.

### **About the Authors**

Peter Emanuel, Mike Mazza, and Karen Poffenberger support the Critical Reagents Program, which is within the Joint Program Management Office, Chemical Biological Medical Systems (CBMS). Dr. Emanuel is the CRP director. He previously served as a research biologist and a scientific advisor at the Edgewood Chemical and Biological Center where he developed an expertise in pathogen detection, biological sampling, and production of antibodies. He has four patents with work in high-throughput robotics and nano-manipulation of bio-test kits.

Mike Mazza, Camber Corporation, is the CRP quality manager. He is responsible for establishing a formal quality management system that integrates and improves business processes across the program.

Karen Poffenberger, Camber Corporation, is the senior systems analyst for CBMS. She is responsible for automating and streamlining knowledge management within the program utilizing an Integrated Digital Environment.✱

# Standardizing COTS Hardware and Architectures for the Navy's Newest Display and Processor Systems

By Steven Froelich, Thomas Armstrong, and Michael Grant

**O**ne of the most challenging problems associated with tactical systems that are based on commercial off-the shelf (COTS) technology and components is sustaining fielded systems over an extended period of time. The short COTS product life cycle and fast-paced introduction of new components results in a continuous cycle of system component obsolescence and new component introduction. Experience has shown that COTS products typically become unsupported and out of production within 2 years and, sometimes, within 6 months.

## Introduction

As the Navy's supplier of mission-critical display and computing infrastructures and the Navy's largest supplier of COTS technology, the AN/UYQ-70 Advanced Display System Program Office and its prime contractor, Lockheed Martin Maritime Systems and Sensors, have delivered more than 4,000 processing and display systems to the fleet. With such a large customer base and associated divergent requirements, it is a monumental effort to inject and maintain standardization among hardware and software elements.

The solution? VME (VersaModule Eurocard). VME is a flexible open-ended computer architecture standard used in commercial, industrial, and military applications worldwide. The architecture defines system communication methods and mechanical specifications through Standard 1014-1987 issued by the Institute of Electrical and Electronics Engineers. AN/UYQ-70V advanced tactical and C41 display workstations and processor systems utilize VME-based COTS systems because they withstand shock, vibration, and extended temperatures better than the buses used in commercial desktop computers, making them ideal for naval tactical systems.

The VME Migration Program was established when the Hewlett Packard (HP) 744 processor was targeted for discontinuance, which provided an opportunity to migrate to a newer, higher performance technology. The VME Migration Program had the goal of benchmarking technology against requirements, standardizing COTS configurations into a single baseline, and requiring individual programs to stay the course once a baseline was set. Figure 1 depicts the process.

The immediate challenge facing this program was how to satisfy the computer processor tech-

nology and system performance requirements of 10 separate Navy program offices during one technology cycle. The VME Migration Program team met this challenge. Drawing upon engineering research gathered as part of its technology insertion process, the team surveyed, benchmarked, tested, evaluated, and qualified a standardized baseline of COTS computer processor technology.

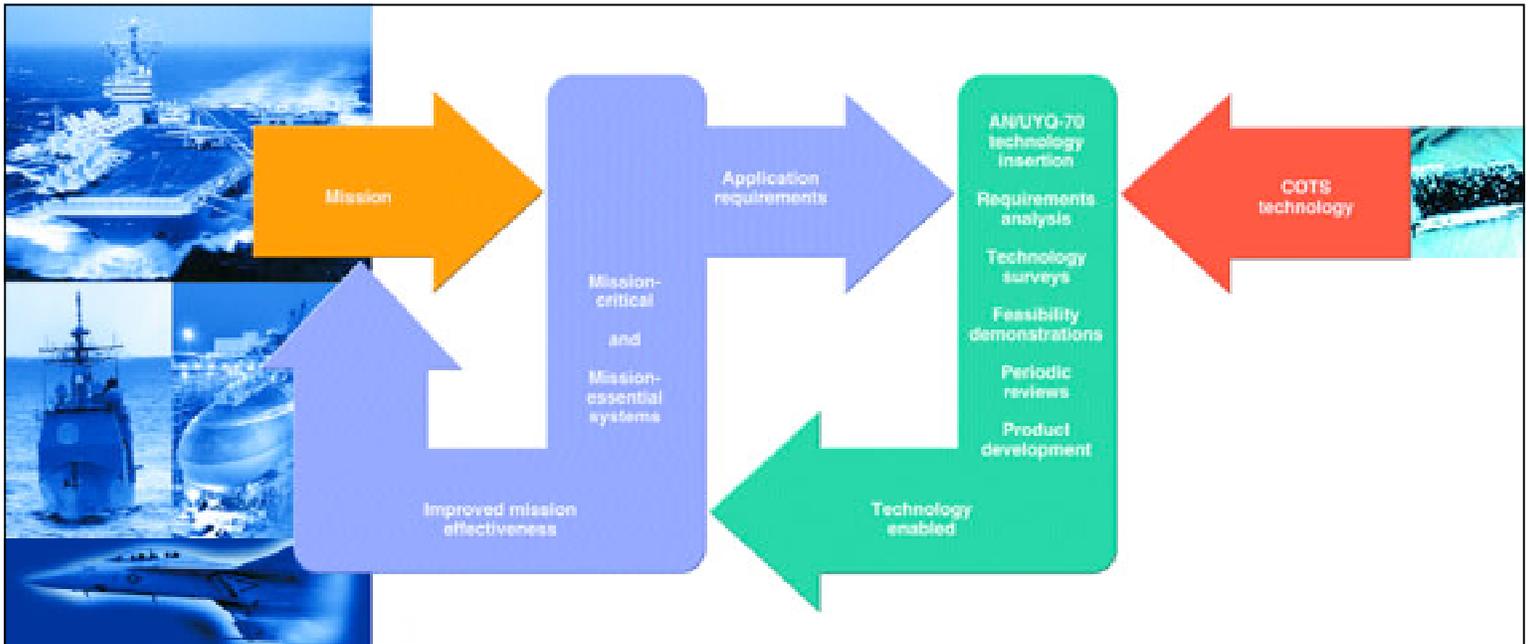
## Challenges

The team encountered three significant problems, each having the potential to derail the VME Migration Program. However, through team commitment and dedication to maintaining a constant flow of information, the technology insertion process kept moving.

### SYSTEM BASELINE MIGRATION

During the VME migration development phase, two technology-driven false starts by the hardware market resulted in three spiral developments of technology:

- *Baseline 1.* The first baseline underwent component-level hardware testing and an operating environment software release incorporating most legacy and new peripheral device drivers and operational parameters. Despite the program's assumption that it had incorporated all the major program schedules, unforeseen slips in the development of combat system programs caused customers to pull back from this baseline and resulted in a delay in technology selection. Transition-to-production activities for this baseline were suspended, and the prime contractor went back to the vendors to capture the next-level available technology.



**FIGURE 1. VME Migration Program's Technology Insertion Process.**

■ *Baseline 2.* A second, more capable baseline was established and tested in multiple customer development laboratories, including Lockheed Martin's Naval Systems Computing Center (NSCC) and the Virginia-class submarine development test sites. The program delivered both engineering development models and production equipment to these sites for test and integration. The submarine community targeted this second baseline for production use. However, the surface community's requirements for an Aegis system with increased processing and memory capacity and reduced obsolescence risk (processor, interface chips, and I/O pinouts) drove the decision to introduce a third baseline as the Q-70 VME migration baseline. Another contributing factor during the decision process was the uncertainty by the vendor (Themis Computer) regarding the stability and longevity of the processor baseline.

■ *Baseline 3.* The last baseline was primarily a product-selection baseline. The VME Migration Program had selected the family of technology and, for the most part, all of the vendors it would use. Recognizing the separation between technology selection and ship introduction, the Aegis program asked for the adoption of this baseline.

### COMPETING PROGRAM REQUIREMENTS

The VME migration hardware had to support the requirements and desires of 10 different Navy program offices—customers with programs involving vastly different types of systems, missions, and environments (air, surface, and subsurface). To ensure a complete definition and understanding of the requirements, the VME Migration Program team held multiple reviews of customer requirements. In addition, the lead engineer held weekly reviews with peers across all programs to ensure that best engineering practices were incorporated.

The team's focus on stakeholder involvement and its care in adhering to a rigorous development and test process ensured the delivery of robust, well-received products.

### ENVIRONMENTAL QUALIFICATION

The technology selected had to meet environmental qualification requirements prior to final approval and shipboard delivery. To the greatest extent possible, the prime contractor pushed environmental qualification down to the COTS suppliers. (Figure 2 contains photos of a shock qualification test.) Initially, there was some concern about this approach, but the major COTS



**FIGURE 2. Shock Qualification Test.**

suppliers supported it, vying for “star” or “most favored” status with a major DoD prime contractor. In many cases, the COTS component manufacturers would pretest candidate technology or invite Lockheed Martin engineers to visit their design and manufacturing facilities. This significantly reduced the time required to qualify systems and reduced the Navy's funding and schedule risks.

### Financial Performance and Acquisition Strategy

With all of the starts and stops, personalities, and demands placed upon the VME Migration Pro-

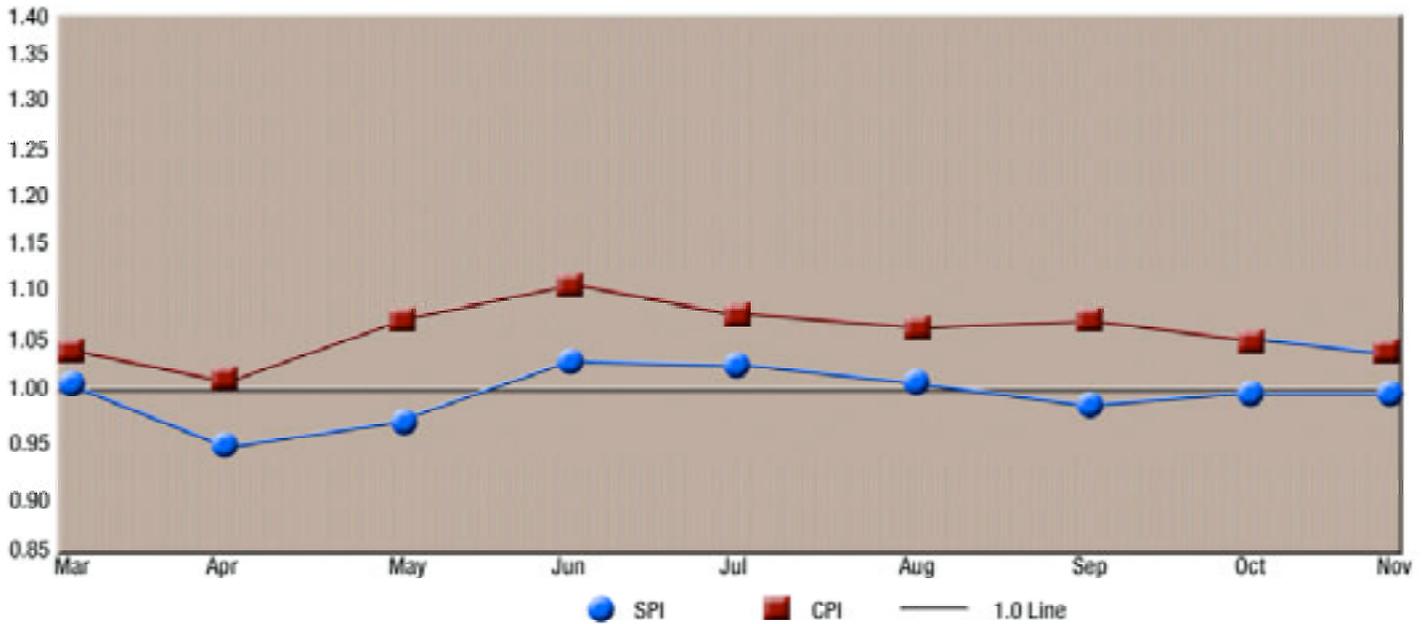
gram, the team completed its non-recurring engineering effort 8 percent under budget.

The success of the VME Migration Program resulted from detailed program planning and meticulous program management. These efforts started with the submission of a detailed statement of work, budgeted work breakdown structure, spend plans, baselined schedules, a basis of estimates (BOE), and a detailed earned-value management plan. Every month, the project manager received a detailed financial performance report; program managers held quarterly program reviews at which program managers reviewed individual performance measures. Internal to Lockheed Martin, the program manager required increased accountability from his engineering and logistics managers through monthly reviews of earned-value metrics and performance against their submitted BOEs. Figure 3 is a graph showing earned-value performance.

Standardization of processor architecture among 10 programs reduced the total ownership cost of all participating Navy programs, resulting in an estimated cost avoidance of \$10 million over 2 years. At the same time, the cost incurred during the design phase remained below 5 percent of the total VME Migration Program cost. Had the VME Migration Program not succeeded in standardizing this technology baseline, each of these 10 programs would have been required to fund individual technology refresh initiatives or, worse, retain obsolete technology due to lack of funds.

### Summary

A high degree of commonality in systems, components, and architectures was achieved through standardization of hardware and software ele-



**FIGURE 3. Earned-Value Performance.**

**Notes:** **SPI:** Schedule efficiency = Budgeted cost of work performed/Budgeted cost of work scheduled.  
**CPI:** Cost efficiency = Budgeted cost of work performed/Actual cost of work performed.  
 An SPI or CPI less than 1.0 reflects unfavorable contract performance.

ments. Standardizing COTS systems across multiple programs required wide cross-functional participation from industry, sponsor program management, engineering, production, and integrated logistics support. Numerous processes were established or improved because of the initiative, including technology assessment, supplier and procurement management, COTS selection, life-cycle support, and cost estimating. The VME Migration Program significantly leveraged DoD's acquisition reform initiatives, resulting in improved system performance, noteworthy cost avoidance to the government, and significant improvement to the financial performance of the Lockheed Martin ruggedized computer infrastructure business segment.

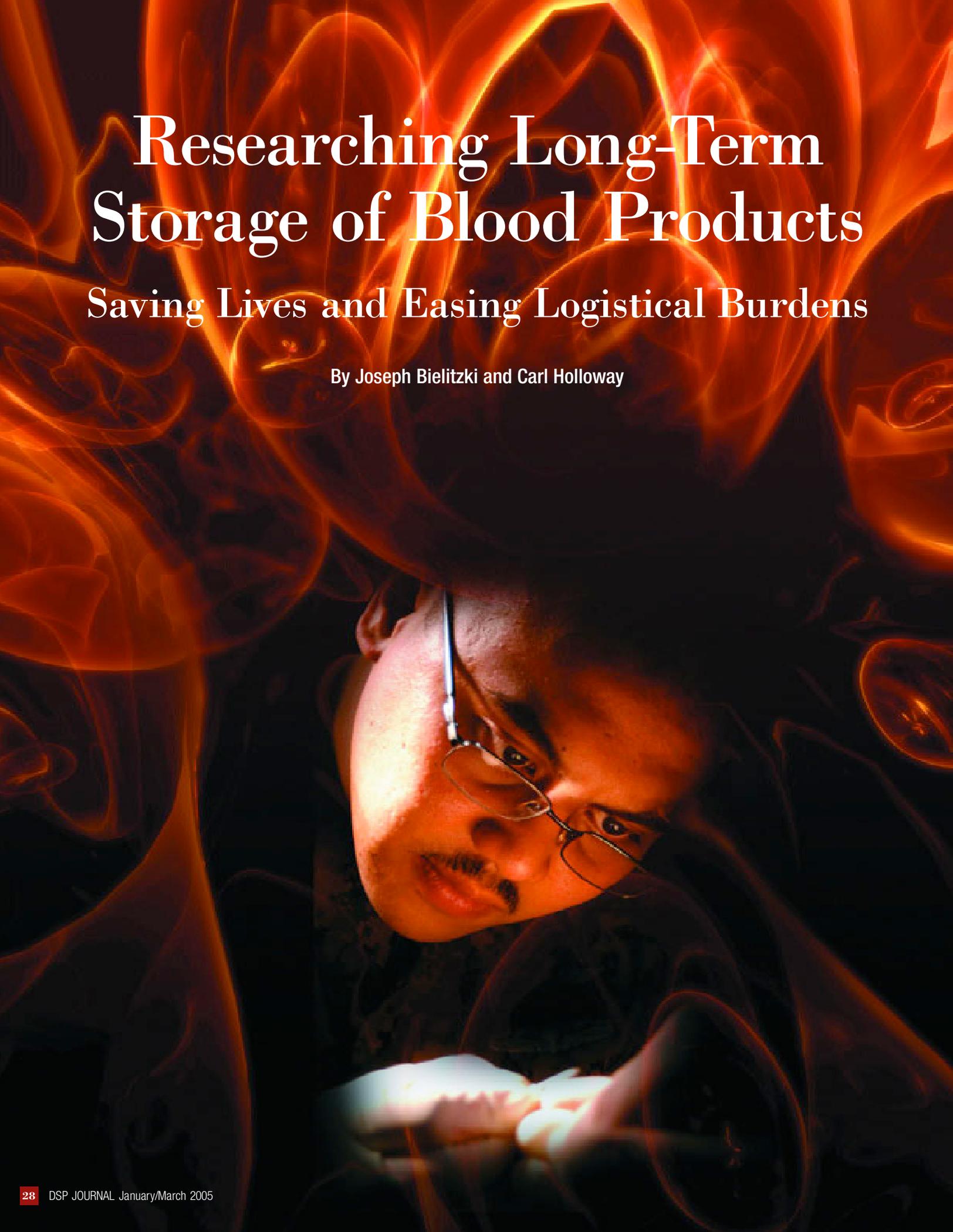
In recognition of the outstanding success of the AN/UYQ-70 VME Migration Program, the team was the recipient of one of the 2003 Defense Standardization Program Achievement Awards.

#### About the Authors

Steve Froelich is the manager of the Q-70 Surface Combatant Program for Lockheed Martin Maritime Systems and Sensors, Eagan, MN. He joined Lockheed Martin after a successful 21-year career in the U.S. Navy as a surface warfare officer.

Thomas Armstrong is the head of the Processors and Display Division in the Program Executive Office for Integrated Warfare Systems. He has worked on Navy processors and displays for over 30 years.

Michael Grant is a program manager for EG&G Technical Services, Inc. He has 24 years of active duty experience in the naval submarine service and was commanding officer of USS Mariano G. Vallejo (SSBN 658).✱



# Researching Long-Term Storage of Blood Products

## Saving Lives and Easing Logistical Burdens

By Joseph Bielitzki and Carl Holloway

Military medicine is hampered by the logistical burden of moving and maintaining refrigerated units of blood and blood products throughout all parts of the globe. The Defense Advanced Research Projects Agency (DARPA) is addressing this issue in its Long-Term Storage of Blood Products research program. The program's investigators have worked for the past 3 years surveying the natural mechanisms used by extremophilic organisms to survive in harsh environments and then applying those mechanisms to blood cells. Their goal is to produce human blood products with a shelf life of several years when stored without any specialized equipment at room temperature. So far, this innovative DARPA program has been successful with platelets and red blood cells—and successes with other blood components are not far behind.

### **The Problem**

Current standards require blood components, once collected, to be stored, transported, and processed under strict guidelines.<sup>1</sup> These standards are written and enforced by the U.S. Food and Drug Administration (FDA) and other elements of the U.S. Public Health Service to ensure the safety of the nation's blood supply. Because blood is a biological product, infectious agents may be present. Therefore, the FDA works to reduce the risk of contamination to the lowest level without unduly diminishing the blood supply.

The guidelines state that collection must occur in a sterile, closed system to protect against the introduction of pathogens or other harmful agents. The guidelines also specify the temperatures for storing and transporting blood products. Platelets must be stored and transported at a temperature of 20°C to 24°C, while other blood components must be kept at 1°C to 10°C. This keeps the bacterial load low and inhibits growth of other microorganisms.

Refrigeration will cause changes in the shape and functionality of platelets, which limits the storage time of platelets to 5 days. The other blood components can be frozen after processing (less than -18°C within 24 hours of collection) and then stored. Some of those blood components can be stored for 21 to 42 days, but frozen red blood cells can be stored for 10 years in 40 percent glycerol, which protects against mechanical damage due to freezing and ice formation. The glycerol must be removed prior to use.

Military regulations for blood products follow the guidelines outlined by the FDA. The current limited storage capability dictates that the military can stockpile only red blood cells for use in casualty care. The red blood cells must be stored in the frozen state and processed with special equipment prior to transfusions.

## DARPA's Solution

DARPA's vision was to find a method to freeze-dry the various blood components so that they could withstand storage in sterile conditions at ambient temperature and could be put to use without the need to remove additives. This would relax the need for storage equipment (with strict regulations, including the use of monitoring and alarm systems, on maintaining temperature) and allow the use of red blood cells, as well as platelets and nucleated cells, for military medical needs.

Platelets and nucleated cells perform many important physiological functions of the blood. Platelets function as clotting agents to close wounds or sites where blood loss is occurring and then to secrete growth factors to draw other cell types to the site to engage in wound healing. Nucleated blood cells include the blood-borne mesenchymal stem cells that can seek out sites of injury and regenerate tissue needed for repair.

DARPA would like to provide freeze-dried products of all three blood products (red blood cells, platelets, and nucleated cells) so that military medical personnel will have adequate supplies to treat casualties at far forward locations. In addition, the availability of such products will protect the injured from blood products from foreign supplies that could be stored under conditions not acceptable in the United States and that possibly are contaminated with pathogens. The platelet product provides the capacity to treat noncompressible wounds, while the nucleated cells provide the capacity for better and faster wound healing and, potentially, treatment for radiation exposure.

To realize its vision, DARPA funded several prestigious institutions—including the University of California at Davis, Virginia Polytechnic Institute and State University, Harvard Medical School, and Uni-

versity of Wisconsin at Madison—to survey extremophilic organisms. The survey focused on the organisms' production of a naturally occurring sugar called trehalose.<sup>2</sup>

Trehalose is most commonly found in the brine shrimp larvae (*Artemia sp.*). Brine shrimp live in areas of high salinity and survive extreme dry periods by forming a cyst and becoming metabolically inactive. They accomplish this by synthesizing large amounts of trehalose, which protects cellular structures that normally would require water to maintain proper shape.<sup>3</sup> The most significant structure protected is the cell membrane. Any damage to the cell membrane during freeze-drying results in a loss of the cell during the rehydration process.

Trehalose not only keeps the cell membrane intact, it is naturally used by the cell as a carbohydrate and consequently does not need special treatment for removal before human use. This means that blood cells can be freeze-dried after they are loaded with trehalose, stored in a sterile bag at room temperature (current testing has gone out to 2 years), and then rehydrated and prepared for use simply by adding sterile water. If DARPA is successful, it will give military personnel the ability to store blood and blood products for extended periods of time, to carry them into any situation in any environment, and to use them on the spot without needing special refrigeration or rehydration equipment.

## FDA's Role

Once the program has been successfully completed, the FDA will develop new standards for processing, storing, and handling freeze-dried blood components. Because the current regulations deal with the temperature and duration of storage, the Blood Action Plan at the FDA's Center for Biologics Evaluation and Research will have to be significantly updated. However, the main safety standards will

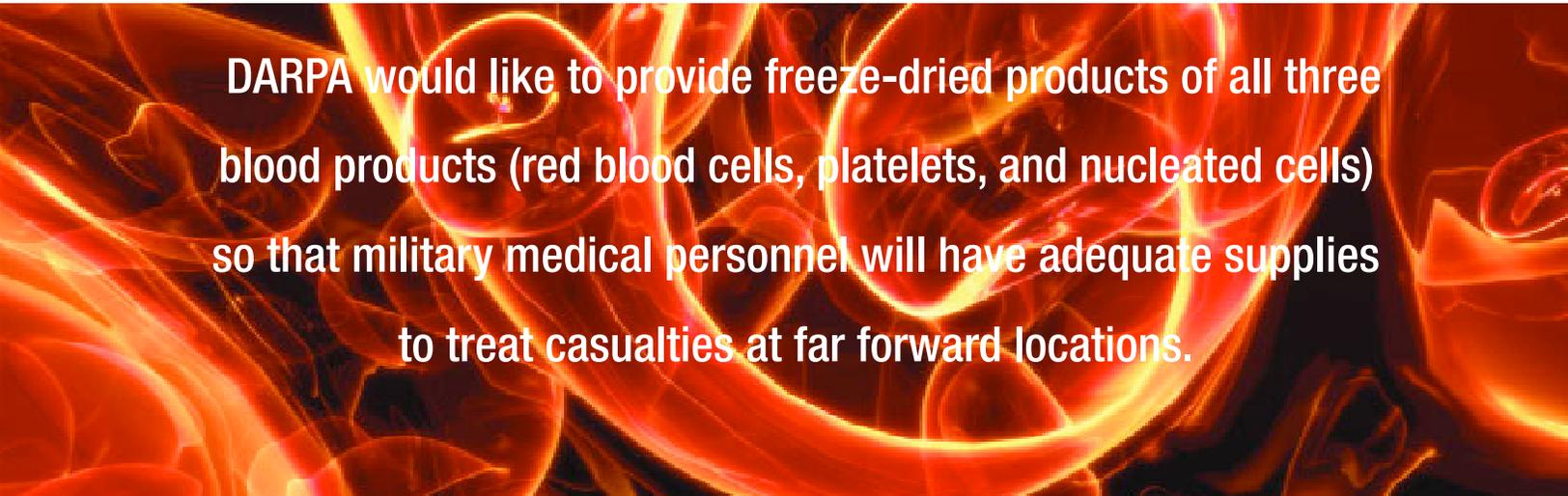
probably focus on the initial processing of the trehalose-treated blood products and safety inspections of the facilities where this occurs. Because freeze-drying trehalose-loaded platelets is innovative, it is hard to determine what standards the facilities will have to follow, but it will focus on keeping the collection system closed and sterile. Collection of blood and blood products will not be changed.

Considering current guidance for platelets, a number of evaluation markers probably will be assessed for the platelets. For example, platelet morphology will be assessed and different morphological forms quantitated. A number of biochemical tests, such as determining the level of lactate dehydrogenase, can

Once these assessments are made, then there need to be enough functional platelets ready for use, currently estimated at more than 20,000 cells/ $\mu$ l. Storage containers will have to maintain the sterile conditions of platelets; currently, the focus is on properly sealing the containers. Sterility of rehydrated platelets will also be considered, again probably focusing on a closed system. Then, the functional ability of the rehydrated platelets will have to be assessed.

### **Program Status**

DARPA's Long-Term Storage of Blood Products program is nearing completion. The technology is being successfully applied to platelets, and the product is nearing the preclinical testing required for



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be used to determine the level of cell lysis. If the procedure activates the platelets, they could cause potentially harmful thrombogenic events. To guard against such events, surface antigens (GMP-140, CD63, and the active form of GPIIb/IIIa) will probably be measured because they are expressed only when the platelets are activated. More important, the functional ability of the platelets will be tested by assaying aggregation in response to agonists such as adenosine triphosphate, collagen, or epinephrine.

FDA review. Red blood cells should reach the same point within 18 months, and nucleated blood cells within 2 years.

The need for more efficient storage of red blood cells and other blood products has been recognized for some time. The DARPA investigations using trehalose have been done while efforts were underway to explore the chemical fixation and the freezing of blood cells. Chemically fixed cells may be problematic and have limited application. Frozen cells, while

possessing a comparable shelf life, still require equipment and time to remove the chemicals used to protect the cells in the freezing process. Trehalose, on the other hand, is labeled by the FDA as a GRAS compound (generally regarded as safe).

Once the trehalose-treated cells reach regulatory review by the FDA, the focus will be on risk-benefit analysis. Do these cells pose any safety problems, and if they do, how much of that risk would be acceptable to treat a given injury? This will be assessed through transfusing DARPA's cells, treated with trehalose and freeze-dried for a specific amount of time, into a healthy animal model and determining if any adverse events are initiated. This will progress into human safety studies, which will be followed by studies examining the efficacy of the cells in treating injuries stemming from blood loss. Once the FDA has approved this method, the product will be scaled

up, commercialized, and made available to military medical personnel.

<sup>1</sup>American Association of Blood Banks, *Standards for Blood Banks and Transfusion Services*, 23rd Edition, 2004.

<sup>2</sup>J.H. Crowe et al., "Anhydrobiosis," *Annual Review of Physiology*, 54:579–599, 1992.

<sup>3</sup>J.H. Crowe et al., "Stabilization of Dry Phospholipids Bilayers and Proteins by Sugars," *Biochemistry Journal*, 242:1–10, 1987.

### About the Authors

Dr. Joseph Bielitzki is a program manager in DARPA's Defense Sciences Office. Previously, he served as chief veterinary officer for the National Aeronautics and Space Administration. He has more than 25 years of veterinary experience.

Dr. Carl Holloway is a senior scientist at Strategic Analysis, Inc. He serves in an advisory capacity to DARPA's Defense Sciences Office. Dr. Holloway has also served in the Center for Biologics Evaluation and Research, U.S. Food and Drug Administration. ✨

# World Standards Day 2004

On October 13, 2004, the Department of Defense joined with its industry partners and other federal agencies to observe World Standards Day at the U.S. Chamber of Commerce in Washington, DC. The goal of World Standards Day is to raise awareness of the importance of global standardization to the world economy and to promote its role in assisting business, industry, government, and consumers worldwide.

World Standards Day is part of a global celebration organized by the International Organization for Standards, based in Geneva, Switzerland. Events are coordinated and funded by the World Standards Day Committee, consisting of representatives from more than 50 major companies, professional and technical societies, trade associations, standards-developing organizations, and government agencies. The event was cosponsored in the United States by the American National Standards Institute and the National Institute of Standards and Technology, and the administrating organization was the Aerospace Industries Association.

At a special U.S. Standards Day reception and dinner, the winners of the Ronald H. Brown Standards Leadership Award and the World Standards Day paper contest were announced.

Simon Pugh, Vice President, Infrastructure and Standards, for MasterCard International's e-Business and Emerging Technologies group, received the Ronald H. Brown Standards in Leadership Award. The award, named in honor of the former U.S. Secretary of Commerce, recognizes leadership in promoting the important role of standardization and eliminating global barriers to trade. Previous award winners have included chief executives of other major corporations—for example, John Deere, Boeing Company, Marriot Corporation, Tenneco, Ameritech, AMP Inc., Motorola, and Polaroid—and federal agencies such as the Department of Commerce.

The purpose of the World Standards Day paper contest is to raise awareness of the importance of standards and present various perspectives on issues of national and international standards. The first-place award went to Alicia Clay and Michael Hogan, coauthors of "Securely Connecting the World with Cyber Security Standards." John Douglas, of the Aerospace Industries Association, presented the award, which included a plaque and a check for \$2,500.



# ANSI Discounts from GSA Agreement

In August 2004, the General Services Administration signed an agreement with the American National Standards Institute (ANSI) to allow all government agencies to purchase standards from the ANSI eStandards Store at discounted prices. Key points of the agreement follow:

- Purchases require the use of either a credit card or a deposit account.
- All federal purchasers use the same discount code—264232.
- Users get a 21.25 percent discount on certain collections of standards, including all standards published by the International Organization for Standardization and the International Electrotechnical Commission, as well as American National Standards in such areas as information technology, encryption, gears and manufacturing technology, and photographic, imaging and optical equipment.
- Users get a 2 percent discount on any other product offered by the ANSI eStandards Store.
- ANSI customer support is available during normal business hours.

For more information, please e-mail [info@ansi.org](mailto:info@ansi.org) or go to the eStandards Store website: [webstore.ansi.org](http://webstore.ansi.org).

## Upcoming Events and Information

### **April 19–21, 2005, Deerfield Beach, FL** *PSMC Conference*

The Parts Standardization and Management Committee Conference will take place on April 19–21, 2005, at the Hilton Deerfield Beach/Boca Raton in Deerfield, FL. For more information, contact Lee Gray at [lee.gray@us.army.mil](mailto:lee.gray@us.army.mil) or visit the PSMC website at [www.dsccl.dla.mil/psmc](http://www.dsccl.dla.mil/psmc).

### **May 9–11, 2005, Washington, DC** *SAE Government and Industry Meeting*

The Society of Automotive Engineers will be hosting its Government and Industry Meeting on May 9–11, 2005. The meeting will be held at the Loews L'Enfant Plaza Hotel in Washington, DC. For more information, or to register, please go to [www.sae.org/events/gim/registration.htm](http://www.sae.org/events/gim/registration.htm).

## People in the Standardization Community

# People

### **Welcomes**

**Stella Romero** recently was named to head the Departmental Standardization Office for the Defense Threat Reduction Agency—formerly the Defense Nuclear Agency. She is responsible for policies governing specifications and standards pertaining to nuclear surety. Since 2003, Ms. Romero served as the lead cataloger for the Nuclear Ordnance Cataloging Office. She has 25 years of federal service and 13 years of standardization program experience. Among other things, she has served as a member of the DoD Item Reduction Program and the Defense Standardization Program Strategic Plan Integrated Process Team.

**Richard Decker** has been selected to succeed Joseph Wienand as Standards Executive of the U.S. Army Edgewood Chemical Biological Center. He has more than 25 years of experience in industry and government. Much of Mr. Decker's experience has focused on the acquisition of chemical-biological protective equipment and smoke-obscuration equipment.

### **Farewell**

**Fernando Alvarado** will be retiring from DoD after nearly 38 years of service. Mr. Alvarado began his government career in the U.S. Air Force and served for 10 years in the munitions field. In 1978, he started working for the Defense Nuclear Agency, now the Defense Threat Reduction Agency, as a nuclear ordnance cataloger. He assumed his present position as chief of Nuclear Cataloging and Standardization in 2001. His office serves the Departmental Standardization Office and Lead Standardization Activity in areas pertaining to nuclear ordnance.

## DAU Courses—2005

	<b>Number</b>	<b>Start Date</b>	<b>End Date</b>	<b>Location</b>
<b>PQM 103—Defense Specification Management</b>	05-002	4/19/2005	4/29/2005	Fort Lee, VA
	05-701	5/10/2005	5/20/2005	Columbus, OH
	05-702	6/13/2005	6/23/2005	Philadelphia, PA
	05-003	7/12/2005	7/22/2005	Fort Lee, VA
	05-703	8/2/2005	8/12/2005	Columbus, OH
	05-704	8/22/2005	9/1/2005	Philadelphia, PA
<b>PQM 212—Market Research for Engineering and Technical Personnel</b>	05-702	4/5/2005	4/6/2005	Robbins AFB GA
	05-703	8/16/2005	8/17/2005	Linthicum, MD

# Upcoming Issues— Call for Contributors

We are always seeking articles that relate to our themes or other standardization topics. We invite anyone involved in standardization—government employees, military personnel, industry leaders, members of academia, and others—to submit proposed articles for use in the *DSP Journal*. Please let us know if you would like to contribute.

Following are our themes for upcoming issues:

Issue	Theme	Deadline for Articles
July–September 2005	Air Force Standardization	February 15, 2005
October–December 2005	The Program Manager	May 15, 2005
January–March 2006	International Standardization	August 15, 2005
April–June 2006	DLA Standardization	November 15, 2005

If you have ideas for articles or want more information, contact Tim Koczanski, Editor, *DSP Journal*, J-307, Defense Standardization Program Office, 8725 John J. Kingman Road, Stop 6233, Fort Belvoir, VA 22060-6221 or e-mail [DSP-Editor@dla.mil](mailto:DSP-Editor@dla.mil).

Our office reserves the right to modify or reject any submission as deemed appropriate. We will be glad to send out our editorial guidelines and work with any author to get his or her material shaped into an article.

