



# MACHINATORRES VITAE

Engineer and Architect Newsletter

## From the Chief Engineer Officer



Sven E. Rodenbeck, Sc.D., P.E., BCEE  
Rear Admiral, US Public Health Service  
Assistant Surgeon General

December 2009

### INSIDE THIS ISSUE:

<i>Message From the Chief</i>	1
<i>EPAC Chair Update</i>	3
<i>Engineering at the Food and Drug Administration</i>	5
<i>Preparing for Promotion</i>	13
<i>Direct Access for Dummies</i>	15
<i>Hoover Dam Bypass</i>	18
<i>New Engineer Officers</i>	21

### To Know Where We Are Going, You Need to Know Where We Have Been

It is a humbling experience and an honor to be selected as the 12<sup>th</sup> Chief Engineer for US Public Health Service (PHS). However, it is comforting to know that I don't stand alone because the previous Chief Engineers have provided me with a firm foundation to continue to build upon. In addition, I have the great fortune to be selected to lead the best cadre of engineers and architects that any Chief Engineer could ever hope for.

To help focus our efforts over the next four years, I have identified three goals:

- We will Reflect upon our past accomplishments as we prepare for our 100<sup>th</sup> Anniversary as a category;
- We will Renew our efforts to recruit even more engineers and architects and advance the engineering and architectural sciences, and
- We will Respond to the ever changing health needs of our country.

Reflecting upon how PHS engineers and architects have protected, promoted and advanced the health and safety of our Nation will allow us to continue to build upon our significant legacy. This legacy is best illustrated by looking at the "20<sup>th</sup> Century Ten Great Public Health Achievements" identified by Centers for Disease Control and Prevention's (CDC) (Source: CDC Morbidity and Mortality Weekly Report 1999;48:241-3):

(Continued on page 2)



1. Vaccination
2. **Motor Vehicle Safety**
3. **Safer Workplaces**
4. **Control of Infectious Diseases**
5. **Decline in Deaths from Coronary Heart Attacks**
6. **Safer Healthier Foods**
7. **Healthier Mothers and Babies**
8. Family Planning
9. **Fluoridation of Drinking Water**
10. Recognition of Tobacco as a Health Hazard

The majority of these could not have been accomplished without the direct and innovative leadership of engineers and architects (bolded items above).

For example, the Indian Health Service Sanitation Facilities Construction program has had a major impact on improving the health of Native Americans by providing safe drinking water to their homes. This has resulted in over a 400% decrease of postneonatal mortalities.

In 1948, PHS engineers participated in the first large scale air pollution study that occurred in the United States. The study was conducted after 120 people died and more than 6,000 became ill when noxious smog developed in Donora, Pennsylvania (Mullan F. Plagues and Politics, The Story of the United States Public Health Service. New York: Basic Books, Inc., 1989.). This ground breaking investigation has served as the foundation for how future air pollution studies have been conducted. In addition to various respiratory diseases, health studies have documented how air pollution is a contributing factor to coronary heart disease (Simkhovich BZ, Kleinman MT, Kloner RA. Particulate air pollution and coronary heart disease. *Cardiology*. 2009;24(6):604-9.).

More recently, PHS engineers and architects were significant contributors to the development of the 2009 *Surgeon General's Call to Action to Promote Healthy Homes* (<http://www.surgeongeneral.gov/topics/healthyhomes/index.html>). Members of the Engineer Professional Advisory Committee (EPAC) began the process that eventually led to the issuance of the *Call to Action*. They proposed and developed the EPAC Healthy Building Initiative. They then coordinated the 2005 *Surgeon General's Workshop on Healthy Indoor Environment*. Based upon the findings of that *Surgeon General's Workshop*, the Surgeon General decided that public health could be significantly improved if we as a nation paid more attention to how our homes are impacting our health. Hence, the *Call to Action* outlines the next steps of a society-wide approach to healthy homes that will result in the greatest possible public health impact and reduction of disparities in the availability of healthy, safe, affordable, accessible, and environmentally friendly homes. In response to the *Call to Action*, the US Department of Housing and Urban Development has already made significant changes in how it manages its vast housing stock.

I look forward to having active involvement from all engineers and architects (Commissioned and Civil Service) as we continue to promote, protect, and advance the health and safety of our Nation. Only by sharing our collected knowledge and ideas will we be able to build upon our proud legacy.

**Machinatores Vitae!!**  
(Engineering for Life)



## 2009 EPAC Chair

CDR John Longstaff

### The End of the Tour...

Well gang, it's come. My final article as EPAC chair. I'll try to hold my profundity to a carefully metered level.

My term as Chair of the EPAC has been unexpectedly brief. Most of the time the job was simply keeping track of the big picture by keep up with what the rest of you were up to. The Engineers are a motivated group, and several took their subcommittees and really ran with them. And that made my job easy.

I suppose every end of the road article needs the requisite 'thank you's' so;

I want to start by thanking RADM (now retired) Rick Barror for his tenure as Chief Engineer Officer. As many of you know I've been acquainted with Rick for longer than several of you out there have been alive. He chaired my commissioning board. He signed the document retaining me after my probationary period ended. When I was driving the Surgeon General around, the SG was in the back seat talking with Barror on the phone! When I got the opportunity to chair the subcommittee to put on the 2006 Engineer/Architect Leadership Development Seminar, Admiral Barror was pretty hands-off and gave me a long leash in putting it together. With occasional exception I was told simply to get it working and report back what I'd accomplished. I think I gained more in the area of Leadership Development that anyone else in attendance as a result. Other people who accomplished similar projects under his lead will likely report the same.

I'd like to next thank the Chairs and members of the EPAC Subcommittees. You are the worker bees who make the EPAC shine the way it does. From the **Career Development** Sub preparing and welcoming new officers, **Readiness** helping to get them ready to be deployable, **Mentoring** helping them grow, **Recruitment** helping us grow, **Awards** recognizing some of the brighter stars amongst so many bright stars, **Public Health Engineering Practices** showing us the way, **Information** keeping us connected and up to date, The ad-hoc **Leadership Development Seminar** sub spreading Engineering Leadership to all Categories across the Corps, and **Rules** keeping us from getting too full of ourselves. You've all done great things and I've no doubt that will continue. You've made my job easy.

Next, I've got to say that a good recording secretary is a magnificent thing, and I've been amazingly fortunate to have had the best: LT Kimberly Love. She is an ambitious up-and-comer who's got more irons in the fire than the stockyard on branding day, and seems to handle it without breaking a sweat. She says she uses magic elves to get things done, and I have no choice but to believe. You've made my job easy.



(Continued on page 4)



I've met many new junior engineers and found them to be are bright, forthcoming, have enormous enthusiasm and a very different perspective from the officers I knew when I first came in. The new Corps is coming, and they're it. It's from these encounters that I have great confidence in the future of the category.

I must give much credit to the outstanding support I've received from RADM (upper half, retired) Gary Hartz, and the engineers of the IHS. From ceremonial events to deployments to special projects, Admiral Hartz has always been right behind the EPAC with support and/or funding, and with hardly a question or whimper. You made my job easy!

I've also been exceptionally fortunate for my immediate supervisor, CAPT José Cuzme, a past EPAC chair himself who never saw conflict between my "day job" and EPAC and corps responsibilities. You too have made my job easy.

I want to take a minute to point out RADM (ret) Jerry Michael. I don't know of any other person so wholeheartedly behind the corps and the Engineers specifically. Even though he retired many years ago, he keeps participating and coming to just about every event that takes place, because, in his words "They keep paying me...". You're an inspiration.

I'd be quite negligent if I failed to welcome RADM Sven Rodenbeck to his new additional duty as Chief Engineer Officer. Essentially you've agreed to a four year hitch with more authority, more responsibility, and no budget. You've been of great help to me in the past, and I know the engineers will be in good hands under your oversight.

As I end this term, I want to welcome the newest members of the Committee who will start their terms at the beginning of the calendar year: CDR Eric Shih, LCDR Nathan Epling, CDR Robert Hemberger, LT Kimberly Love, CDR Kenneth Sun, and LT Nazmul Hassan. I encourage you all to be very involved, and you'll find that your growth in connection to the category will be the greater for it, and both you and the category will benefit.

Lastly, I want to welcome CDR Hilda Scharen to the Chair. At around the time of publication of this article you will assume the Chair of EPAC. While it is an additional workload, I know you're quite up to it. The job is lots of work but I've never heard any that regretted doing it. Your work chairing other EPAC Subcommittees including Information, Rules, and Leadership Development Seminar, have given you a good perspective on the EPAC as a whole. Plus, you've got all of those people I mentioned earlier to make your job easy, to include your new Vice Chair and master henchman, CDR Peter Nachod. I'm ready to move into a role of advisor/assistant, I look forward to helping you fly through a year of the easiest job you'll ever fret over. Welcome Hilda!

And to the rest of you I encourage you to get involved in EPAC activities/subcommittees, as well as other Corps and or professional associations, including COA, SAME, or others. Yes, you'll be busy, but you'll know so much, and you'll never regret taking on the extra contacts and exposure.

Thank you all for the opportunity to do this job, if only for a year. It's been my honor to serve. Help others succeed, and they won't be the only ones helped.

Machinatores Vitae!



## Engineering at the Food and Drug Administration

CDR Emil Wang

The Food and Drug Administration (FDA), one of our Nation's oldest consumer protection agencies, ensures the safety of foods, cosmetics, pharmaceuticals, biological products, and medical devices. The FDA also substantiates the efficacy of pharmaceuticals, biological products, and medical devices. The FDA is a regulatory agency that enforces the Federal Food, Drug, and Cosmetic Act and other laws administered by the FDA. Its employees monitor the manufacture, import, transport, storage, and sale of about \$1 trillion worth of products each year, about 25% of consumer expenditures in the U.S. In total, FDA has over 10,000 employees.

Organizationally, the FDA consists of the following Centers and Offices that regulate specific product commodities, perform research, and conduct field activities.<sup>1</sup>

**The Center for Biologics Evaluation and Research (CBER)** regulates biological products for human use that include allergens, blood and blood products, cellular and gene therapy products, tissue and tissue products, vaccines, and xenotransplantation.

**The Center for Devices and Radiological Health (CDRH)** regulates firms who manufacture, repackage, relabel, and/or import medical devices into the U.S. CDRH also regulates radiation-emitting electronic products, medical and non-medical, such as lasers, x-ray systems, ul-

trasound equipment, microwave ovens, and color televisions.

**The Center for Drug Evaluation and Research (CDER)** regulates over-the-counter and prescription drugs, including biological therapeutics, generic drugs, and other products considered "drugs," for example, fluoride toothpaste, antiperspirants, dandruff shampoos, and sunscreens.

**The Center for Food Safety and Applied Nutrition (CFSAN)** is responsible for ensuring that the Nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled. Its responsibilities include the safety of food, substances added to food, e.g., food additives (including ionizing radiation) and color additives, ingredients developed through biotechnology, dietary supplements, infant formulas, and medical foods.

**The Center for Tobacco Products (CTP)**, the most recent addition to FDA, regulates tobacco products by setting performance standards, reviewing premarket applications for new and modified risk tobacco products, requiring new warning labels, and establishing and enforcing advertising and promotion restrictions.

**The Center for Veterinary Medicine (CVM)** regulates the manufacture and distribution of food additives and drugs that are given to animals, including animals from

*(Continued on page 6)*



which human foods are derived as well as drugs, devices, or food additives given to, or used on, companion animals, poultry, cattle, swine, and other minor animal species.

**The National Center for Toxicological Research (NCTR)** performs research to develop scientifically sound bases for regulatory decisions and to reduce risks associated with FDA-regulated products.

**The Office of Regulatory Affairs (ORA)** is the lead office for all field activities. The ORA provides agency leadership on imports, inspections, and enforcement policy while supporting the product Centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the U.S. The ORA has 5 Regional Offices, 20 District Offices, 13 Laboratories, and more than 150 Resident Posts and Border Stations throughout the U.S., U.S. Virgin Islands, and Puerto Rico.

**The Office of the Commissioner** contains, among other Offices, the Office of International Programs which leverages the activities and resources of trusted foreign counterpart regulatory authorities in China, India, the Middle East, Europe, and Latin America to establish a permanent in-country presence in these areas.

So what qualifications does an engineer need to work for FDA?

Basic requirements for all engineering positions at FDA include successful completion of a full 4-year professional engineering curriculum leading to a bachelor or higher degree in engineering in an accredited college or university, OR a combina-

tion of education and experience — college-level education, training, and/or technical experience that furnish:<sup>2</sup>

- a thorough knowledge of the physical and mathematical sciences underlying professional engineering
- a good understanding, both theoretical and practical, of the engineering sciences and techniques and their application to one of the branches of engineering.

To be an engineer officer in the U.S. Public Health Service (PHS), a bachelor's or master's degree in engineering must be from an engineering program accredited by the Accreditation Board for Engineering and Technology (ABET).<sup>3</sup>

In addition to the educational training requirements, engineers should have the following skills:

- ✓ An understanding of regulatory science, i.e., how to make science-based decisions within the requirements of FDA laws and regulations.
- ✓ Effective communication skills, both oral and written, are essential to document technical reviews and to communicate with agency and regulated firm officials, firm counselors and consultants, special interest groups, Congress, and the public.
- ✓ Leadership and teamwork in directing reviews with consulting medical officers and technical experts, performing inspections and investigations, and conducting research.
- ✓ Time and project management in prioritizing assignments to complete them on-time, with timeframes often defined by legislation or policy, or in response to a public health emergency.

(Continued on page 7)



Meet a few of our engineers:

**CAPT Mutahar Shamsi**, Biomedical Engineer, is the Director of New England District Office's Compliance Branch, ORA, at FDA. His staff has been instrumental in developing over 56 actions for violations of regulatory significance over the past 3 1/2 years. In just the medical device area alone, this included a \$74 million civil settlement from a medical device firm for distributing adulterated cardiovascular devices; a seizure of over \$1 million worth of adulterated and misbranded electrical muscle stimulators; a consent decree of permanent injunction of an X-Ray equipment manufacturer; a Corporate Wide Warning Letter against a device company that continually violated FDA regulations at most of their manufacturing facilities nationwide.

CAPT Shamsi started his PHS career 24 years ago as an engineering analyst at the Winchester Engineering & Analytical Center where he tested medical equipment such as thermometers, sphygmomanometers, X-Ray equipment and ventilators. Since engineers are familiar with computer systems, CAPT Shamsi filled a need at the Boston District Office by helping to manage their information systems as well as developing databases for office use. An engineering background compliments the job of an FDA investigator. For example, FDA investigators evaluate schematic drawings, review test data, observe manufacturing processes, scrutinize validation protocols and results, and explore adverse events. As an FDA investigator, CAPT Shamsi has travelled throughout New England, the US and abroad conducting inspections of hundreds of device manufacturers such as patient monitors, computed tomography systems, blood bank software, retinal implants, heart valves, cardiac

stents, in-vitro diagnostics, living skin equivalents and bone morphogenic proteins. It is up to an investigator to make an appropriate decision as to whether or not the manufacturer is meeting FDA's laws and regulations. FDA Compliance Officers and Managers need to be convinced that an investigator's work is sound in science and the law.

The discipline of biomedical engineering and the FDA are a perfect fit. Engineers are trained in a vigorous and deliberate thought process which helps in the writing of persuasive reports. CAPT Shamsi noted "In any field, it is important to have a good boss and mentor. I've been lucky to have been supervised by people who have pushed me when needed and listened when asked. Overall, being a U.S. Public Health Service Engineering Officer in the FDA has been a challenging and rewarding career. There are many opportunities to learn and grow both as an engineer and a leader."

**CAPT Andrew Zajac**, Biomedical and Environmental Engineer, is the Director of the Division of Petition Review in the Office Food Additive Safety, CFSAN, at FDA. He was promoted to this position in 2006 after stints in his office as a consumer safety officer and group leader. CAPT Zajac's division is responsible for the safety review of petitions that are submitted by industry seeking approval for new food additives as well as color additives used in food, drugs, cosmetics, and medical devices in the United States. The Division largely consists of P.D.-level scientists trained in the evaluation of these substances.

The approval of an additive in food may potentially affect all U.S. consumers throughout their lifetimes. The FDA must ensure that the amount of the additive that people are

*(Continued on page 8)*



reasonably expected to be exposed to after approval is safe. Based on legislative history, the term “safe” means reasonable certainty of no harm. In determining whether the proposed use of an additive in food is safe, FDA typically compares an individual’s estimated daily exposure to an additive to an acceptable intake level established by toxicological data. A similar type of risk assessment is conducted for color additives to be used in drugs, cosmetics, and medical devices.

The burden to demonstrate that the use of an additive is safe falls on the petitioner, who must provide information on the identity and composition of the additive, use level, functional effect, probable exposure, stability, and, of course, results from toxicity studies. If, after reviewing this information, FDA decides that the proposed use of the additive is safe, a final rule is published in the Federal Register that approves the petitioned use of the additive.

Additives that have gone through this petition process include those that are well known to the public such as the artificial sweeteners Aspartame and Sucralose and the fat substitute Olestra. In the past few years, CAPT Zajac’s division has approved a number of additives, including antimicrobial agents used in or on food and color additives used in food and cosmetics. They are currently immersed in the review of a large petition that was submitted this year for a new artificial sweetener.

CAPT Zajac is the first and only engineer that has ever worked in this office, which primarily hires chemists and toxicologists. He also is the only PHS officer in this office, which makes him even more unique and provides positive exposure for the Corps. While his background is atypical for someone working in his position, he

has proven that an engineer is capable of managing and leading a scientific staff responsible for ensuring the safety of a class of products as diverse as food additives. The next time you find yourself looking at a list of ingredients on a food label, you may think of CAPT Zajac and his dedicated staff at FDA.

**CDR Emil Wang**, Biomedical Engineer, is a Case Expert in the Office of Compliance, CDRH, at FDA since 2008. CDR Wang applies his engineering and legal training and expertise to evaluate all CDRH administrative and legal actions to ensure that they are legally supportable and consistent with agency policy. Examples of these actions include Warning and Untitled Letters, seizures, injunctions, civil money penalties, and import alerts. CDR Wang also provides regulatory counseling by reviewing and responding to citizen’s petitions, reviewing financial statements and reports submitted by medical device firms to the Securities and Exchange Commission, and providing assistance to investigations conducted by the Department of Justice, State and local authorities, and criminal investigations performed by FDA’s Office of Criminal Investigations.

Compliance activities are very dynamic and require the application of logic and analytical skills to evaluate the evidence and circumstances to determine the appropriate enforcement action to take, skills that engineers are well-suited for. The development of enforcement actions requires the application of regulatory science to ensure that the actions are supported by sound evidence and the requirements of the law. The decision to take an enforcement action must also consider how to adequately address the risks posed to public health. This entails inspections of facilities and investigations to collect evidence, review of the evidence by agency compliance

*(Continued on page 9)*



officers with consultation by medical officers and technical experts to determine its supportability and assess the public health risk posed by the violations, and working with agency management and legal counsel in the Office of Chief Counsel to process the enforcement action.

Some of the notable enforcement actions that CDR Wang has successfully implemented include a consent decree of permanent injunction against a Fortune 100 company that manufactures X-Ray surgical imaging systems for violations of the Current Good Manufacturing Practice (CGMP) requirements as set forth in the Quality System (QS) regulation for devices; a consent decree against a manufacturer of automated external defibrillators for QS regulation violations; a \$2.7 million seizure of muscle massagers and electrical stimulators that were unapproved, failed to meet performance standards, and were manufactured in unregistered facilities; and developing and executing an inspection warrant against a firm that promotes and distributes unapproved ozone generator devices for treating medical conditions that poses a danger to health when used in the manner recommended by its labeling.

CDR Wang has spent his entire 14 year PHS career with the FDA. Immediately following graduation, CDR Wang reviewed premarket marketing applications of cardiovascular, anesthesiology, and respiratory medical devices at the Office of Device Evaluation (ODE), CDRH, at FDA. These duties consisted primarily of evaluating scientific data as well as test methods and descriptions of medical devices to determine its safety and efficacy. CDR Wang also served as an investigator in the San Francisco District Office, ORA, at FDA, conducting inspections, investigations, and sample collections of various

commodities regulated by FDA. Memorable experiences from this field work includes performing inspections of medical device manufacturers around Silicone Valley, a well-known sparkling apple cider manufacturer along the Monterey Bay, importers at the Port of Oakland, pre-dawn inspections of seafood establishments on Fisherman's Warf, and performing collaborative import investigations with the U.S. Postal Service, U.S. Customs and Border Protection, and U.S. Fish and Wildlife Service. CDR Wang has also practiced food and drug law at a private law firm.

CDR Wang comments on his FDA career: "FDA has provided opportunities for me to develop my interest in regulatory science by applying my technical, scientific, and legal expertise throughout the total product life-cycle of medical devices. Moreover, my career in the U.S. Public Health Service has developed my leadership skills to become a more effective professional and officer. For these reasons, my engineering career in the Commissioned Corps has been a unique and fulfilling experience."

**Ms. Erin Keith** is a civil service materials engineer. Her academic background in materials engineering has prepared her for numerous positions at FDA, ranging from policy analyst in the Office of the Commissioner, to compliance officer at CDRH, to premarket device reviewer at CDRH.

Ms. Keith currently works in the Commissioner's Office in the Office of International Programs, stationed in New Delhi, India as the U.S. FDA Assistant Country Director for Medical Devices. Ms. Keith is working in India for next two years as part of the Beyond Our Borders initiative to assist in building the Indian industry's and government's understanding of FDA's regulatory require-

*(Continued on page 10)*



ments for medical devices as well as to analyze the Indian industry's and government's current regulatory capacity. In this position, she utilizes her extensive knowledge of medical device regulations and analytical skills developed in her previous positions at FDA.

Prior to her current position in India, Ms. Keith worked at CDRH, initially starting in ODE utilizing her materials engineering knowledge and critical thinking skills in reviewing premarket marketing and clinical study applications for dental and orthopedic devices. The scientific knowledge, critical thinking and decision making skills of an engineer are ideally suited for the work that ODE performs. Some of Ms. Keith's notable ODE assignments include being a lead reviewer for the first dental combination product (device + biologic) investigational device (IDE) application, first spinous process spacer IDE, and first orthopedic humanitarian device exemption (HDE) application for a finger joint replacement device; being a team leader for orthopedic devices; and participating in the Canadian Partnering Program which culminated in her selection for a two month detail assignment with Health Canada's office of device evaluation.

After working in ODE for six years, Ms. Keith transferred to the Office of Compliance where she became the first engineer to achieve the peer review position of Master Reviewer. The scientific and critical-thinking and decision-making skills that engineers possess are particularly useful for analyzing the technical, regulatory and legal information involved in the wide range of assignments in the Office of Compliance. A compliance officer at CDRH must be able to evaluate technical information to determine if a company is meeting its regulatory obligations. Assignments

include CGMP/QS reviews of establishment inspection reports; the development of Warning and Untitled Letters, seizures, injunctions, and civil money penalties; recall classification; researching complaints; and reviewing manufacturing changes. These kinds of assignments require the integration of scientific, technical, regulatory and legal information to complete. Some examples of Ms. Keith's notable assignments in the Office of Compliance include the development of complex warning letters for violations of Investigational Device (IDE), Humanitarian Device Exemption (HDE), premarket approval, Device Tracking, Quality System, Medical Device Reporting, and Recall regulations; evaluation of third party companies seeking to participate in the Accredited Person Auditor program, a program developed for voluntary surveillance QS regulation audits; assistance in the development of a risk management course, Risk Management in a Quality Management System, and being an instructor for the Association for the Advancement of Medical Instrumentation (AAMI) quality system courses; being the lead for managing unprecedented orthopedic recalls stemming from material properties related failures; and successfully completing detail assignments as a Branch Chief and Deputy Division Director.

Ms. Keith's academic training in materials engineering has opened many doors at the FDA, resulting in 15 years of interesting work assignments, professional and intellectual challenges, and a stimulating work environment. Ms. Keith is one example of many illustrating how the skills developed in the engineering disciplines can be successfully applied to the work performed at FDA and can result in an intellectually and professionally rewarding career.

**LT Nazmul Hassan**, Biomedical Engineer,

*(Continued on page 11)*



is a Compliance Officer at the New York District Office, Downstate Compliance Branch, ORA at FDA. He was promoted to this position on 2009. Before taking this new role, he served as a Consumer Safety Officer at the New York District Office Downstate Imports Operation Branch for seven years. LT Hassan is tasked to overlook the API and finished dosage drugs, biologics and drug/device combination products entering U.S. commerce either for commercial or personal use in human or animals.

The U.S. imports \$1.476 trillion worth of goods, making it the largest importing nation in the world. Goods of every description regulated by FDA pour in every day into the jurisdiction of the New York District Office, arriving at the Port of New York and ports of entry along the New York-Canadian border. Consequently, about 33% of all the nation's regulated commodities pass through the New York District Office; and approximately 20% of freight shipments by value of shipments enter the Northeast Region. According to the U.S. Customs and Border Protection, more than 55% of International Mail is processed at the JF Kennedy Mail Facility.

The New York District Office is responsible for facilities located in New York, JFK International Airport, Jamaica, New York and Secaucus, New Jersey; consisting of land, air and ocean ports. The confluence of express mail, other mail services, and the emergence of the internet have dramatically changed the district's operations at these facilities. During the past several years, the volume of unapproved new prescription drugs ordered over the internet from an array of foreign countries has grown dramatically. Additionally, the potential traffic in counterfeit and unap-

proved drugs being sold over the internet is growing. LT Hassan works closely on a daily basis with other government agency partners, such as U.S. Customs and Border Protection, U.S. Postal Service, U.S. Fish and Wildlife Service, FBI, Secret Service and other agencies. He also works with the Office of Criminal Investigations concerning individuals and enterprises employing the mail for commercial purposes concerning the distribution of counterfeit and unapproved new drugs. Illustrations of these activities include human growth hormone and in vitro-fertilization drugs and other risk based drugs.

Products that come from a country known to have serious problems posing health hazards, or from an exporter known to mislabel the imports, or to a particular type of product that has been found violative in previous shipments may be placed on Import Alert, which detains these products without physical examination. When a product subject to an Import Alert arrives, FDA does not sample it; only the documents relating to the shipment are collected. It is then up to the importer to demonstrate to FDA that the product is not violative. FDA maintains a close liaison with U.S. Customs and Border Protection and a sophisticated system of intelligence gathering, storage, and retrieval so that use of inspectional personnel is as efficient as possible. Computers are used to track all samples from collection through lab analysis and eventual disposition

The import arena is complicated and full of challenges. Who else is more prepared to deal with these challenges than a Commissioned Corps Engineer? The knowledge and skills as an engineer has helped LT Hassan to streamline and tackle complex problems in systematic ways. FDA/ORAs gives engineers a variety of choices to become an expert in their respective field and provides numerous

*(Continued on page 12)*



leadership opportunities.

What's the future for PHS officers at FDA?

The FDA is an extremely diverse organization that has direct and immediate impact on protecting and promoting public health and safety, with national and international reach. FDA is an organization that has grown in size and responsibilities through the last century. This is exemplified by the recent establishment of foreign offices and the creation of the new Center for Tobacco Products.

FDA actively recruits qualified health professionals for mission-critical medical and science positions to strengthen its public health mission. Commissioned Corps officers from all professions are assigned to the FDA and serve in various capacities to advance the agency's mission. Currently, among a total of approximately 6,485

Commissioned Corps officers, 876 officers are assigned to FDA, representing the second largest agency in which Commissioned Corps officers serve.<sup>4</sup> Of these 876 Commissioned Corps officers, 59 are engineer officers.<sup>5</sup>

The technical knowledge and critical-thinking and decision-making skills developed in the engineering disciplines are in great demand at the FDA, where these skills can be applied to positions located in numerous offices. Engineer officers are well-suited to meet these challenges and have excelled in traditional and non-traditional engineering roles. Being an engineer officer in the U.S. Public Health Service is challenging and rewarding. As illustrated by the engineer profiles, the breadth of opportunities available at FDA presents many opportunities for personal and professional growth and development.

<sup>1</sup><http://www.fda.gov/AboutFDA/CentersOffices/default.htm>

<sup>2</sup><http://www.fda.gov/AboutFDA/WorkingatFDA/CareerDescriptions/ucm113287.htm>

<sup>3</sup><http://usphs.gov/profession/engineer/requirements.aspx>

<sup>4</sup>[http://dcp.psc.gov/rpt\\_agency\\_by\\_corps.asp](http://dcp.psc.gov/rpt_agency_by_corps.asp)

<sup>5</sup>[http://dcp.psc.gov/rpt\\_agency\\_by\\_category.asp](http://dcp.psc.gov/rpt_agency_by_category.asp)



## Preparing for Promotion

To those folks up for promotion this year the deadline for submitting your file is here and gone, but as this is the time of year when our heads are abuzz with the topic, we thought we'd take this opportunity to talk about what you should be starting now to help in the future. So, to those who will be eligible next year, it's never too early to start shaping your OPF to make sure you put your best foot forward. Those who will be up for promotion for the first time may be asking yourself "What should I be doing to ready myself?" Even those who have been through this process before tend to forget how to put forth the best representation of who you are and what you've accomplished. The list below is a collection of observations from the last engineer promotion board and represents their thoughts on how to best ready yourself for promotion.

1. Submit your Officer Statement.
2. Ensure your CV is current.
3. Make sure your COER is submitted.
4. To the extent possible, ensure the Reviewing Official Statement is submitted.
5. Review your PIR; also check that your rank, awards, etc., shown on the documents submitted by you or about you (i.e. CV, OS, ROS, COER) are consistent. Explain any discrepancies.
6. Ensure information contained in your eOPF is readable on a computer screen—transcripts are frequently difficult to read. This is a problem because they are inconsistent between schools and it is difficult (and time consuming) to determine the actual degree awarded from many institutions.
7. Mentors should consider providing documentation showing their level of participation—possibly a certificate from the EPAC Mentoring Subcommittee describing their level of involvement and progress.
8. While quantity of information presented in the CV and eOPF is impressive to a certain extent, it is more important to ensure that the relevant information is easy to find. As an example, a continuing education sheet that includes computer security training that is presumably required of everyone in your agency makes it difficult to find and interpret the significance of relevant training.
9. It is expected that awards should be received on a regular basis—higher level awards are certainly more impressive, but the regularity of the awards is probably most helpful.
10. Expect to see the P.E. grow in importance with increasing rank. A P.E. is most important for engineers in positions or in agencies where being a registered Professional Engineer is expected. Other relevant professional certification is expected for positions where a P.E. is typically not available.

*(Continued on page 14)*



And the personal thoughts from a single Board member.

11. Billet grade is important, and it becomes more important with each promotion rank.
12. Performance is important; the reviewers need to know whether or not you are meeting your supervisor's objectives.
13. Advanced education and professional registration are important; however, they are most important if they are relevant to your current position or future goals.
14. Seek out opportunities to demonstrate your leadership. Being a member of many organizations is not as impressive as holding a leadership position.
15. Either as a member or a leader, make sure reviewers understand your contribution.

For more information the promotion process, including the recommended engineer CV format and PY10 Benchmarks, please visit the career development page on the engineers website at <http://www.usphsengineers.org/CareerDevelopment.htm>

## Thank You

*The Newsletter Team would like to thank RADM Rick Barror (Ret.) for his support over the last three years. He helped us foster our idea to develop the Machinatorres Vitae newsletter and without his encouragement and assistance we would not have been able to bring it to life. We thank you for the thoughtful insights you provided us through the Chief Engineer column, your patience with the publication process, and your overall dedication to making this endeavor a success.*

*Thank you!*



## Direct Access for Dummies

As you are now aware, the Commissioned Corps has adopted a new information technology system to support Transformation. The Corps has teamed with the U.S. Coast Guard to share the Direct Access human resources system, currently used to manage over 50,000 uniformed personnel.

Direct Access is intended to replace all other Corps personnel systems and provide officers with a single place to log on, enter and review his or her personnel information, indicate career interests, and look for job postings. This ambitious goal will be met through a series of releases that incrementally replace current Corps systems over time.

When fully functional, Direct Access will be used by officers to:

- Enter job preference information to be used by OCCO for help in finding a new job assignment.
- View job postings of available Corps vacancies and save those of interest for further review.
- Review an auto-generated CV that includes the officer's verified data on file in OCCO such as their awards, licensure, certificates, education/degrees, training, memberships, and other skills.
- Update personal info such as addresses, phone numbers, and emergency contacts.
- View/verify other data on file in OCCO such as additional personal information, security clearance information, and job assignment history.

The Corps will use Direct Access to:

- Quickly identify for hiring officials qualified officers for vacancies, potentially enabling more officers to be hired for positions they are qualified for and are interested in (i.e., a successful "match").

- Quickly identify for OFRD qualified officers needed for response roles.
- Provide training and career management for officers by answering the question: "What certifications/skills do our officers currently possess?"
- Achieve integration of systems – Direct Access will serve as the main PHS system for all officers.

So far, the First Phase of the Direct Access project has been successfully completed and more phases are scheduled to come.

### The First Phase

#### *Officer Profiles (Accomplishments)*

In the first phase of implementation, category-specific licenses and certifications were automatically transferred into Direct Access. Additionally, other education, training, and certification information entered by each officer in the Officer Profile (OP) collection tool will be verified and then transferred automatically into Direct Access.

Direct Access automatically generates an eResume for each officer, based upon the information collected. Officers can elect to paste their CVs into eResume to provide additional information. The eResume gives the Corps a "picture" of the whole officer.

For more information, please visit <http://www.usphs.gov/pdf/DirectAccess-Profiles03162009.pdf>

#### *Tell the Corps about your documented accomplishments*

In order to best make use of Direct Access to showcase your skills, please log onto (<https://dcp.psc.gov/cclogin/ccmislogin.aspx>) to create or update your Officer Profile (OP). The OP was launched

(Continued on page 16)



in March 2009 and validated information it collects will be transferred into Direct Access. To receive more details on the OP and find out how to enter your information, please visit [http://usphs.gov/transformation/op\\_faq.aspx](http://usphs.gov/transformation/op_faq.aspx)

#### Officer Self Service

The first phase also gave officers the ability to log in and update their self service information. Direct Access became the system to enter your home/ mailing addresses, home and office phone numbers, and emergency contact information with necessary information being sent back to existing Corps systems. The CCMIS Secure area is no longer the way to enter "Next-of-Kin Information", "Update Contact Information", and "Update Special Skills and Languages."

**Important:** Please note that the **payroll** address may only be changed through the Compensation Branch (<http://dcp.psc.gov/CB.ASP>).

For more about Direct Access Self Service, please visit [http://www.usphs.gov/transformation/self\\_service.aspx](http://www.usphs.gov/transformation/self_service.aspx) or <http://www.usphs.gov/pdf/Compliant%20Version-Self%20Service-06-18-09.pdf> To help you get started, please read the Self Service FAQs at the end of this article.

#### **The Second Phase**

The Second Phase of the Direct Access project is moving forward, and will last until the end of 2010. Functions to be migrated in this phase include Readiness, Awards, Billets, Training, Assimilation Boards, and Promotion Boards.

#### **The Third Phase**

The Third Phase of the Direct Access project will commence at the beginning of 2011 and will include migrations of Other Boards and COERS during this phase.

### Self Service FAQs

#### **How do I access Self Service in Direct Access?**

##### 1. Get your log in information

You will be provided with Direct Access log in information when you enter the CCMIS Secure area (<http://dcp.psc.gov/SecureArea.asp>).

##### 2. Log in to Direct Access at:

<https://ep.direct-access.us/psp/UCGP1PP/?cmd=login&languageCd=ENG>

##### 3. Please change your Direct Access password once you successfully enter Direct Access.

##### 4. Review your information.

Direct Access has generated a summary Resume and contact information for each officer, based upon all the information collected from existing Corps systems. You can view this through Direct Access's Self Service function.

Please review your Resume for completeness. Update your addresses and contact information if needed. Again, please change your Direct Access password if you haven't done so already.

##### 5. What if I want to submit other information?

The Officer Profiles collection tool, available through the secure area of CCMIS (<http://dcp.psc.gov/SecureArea.asp>), will collect additional validated information and transfer that information to the Direct Access information system. For additional information on Offi-

*(Continued on page 17)*



cer Profiles, please see the Commissioned Corps E-Bulletin article, located online at:

[http://dcp.psc.gov/ccbulletin/articles/Initiative Announcement 04 2009.aspx](http://dcp.psc.gov/ccbulletin/articles/Initiative%20Announcement%2004%202009.aspx)

#### **What happens if I cannot log in or forget my password?**

Passwords are provided via email. Please contact PPC Customer Care via e-mail by clicking on the link located at <http://www.uscg.mil/ppc/phs/> for password problems. Please be sure to identify yourself as a PHS officer and provide your serial number and/or Direct Access user ID if available.

#### **Is there a user guide for Self Service?**

Yes. Please go to the PHS Self Service Procedure Guide, Ver. 3.0 located at <http://www.uscg.mil/ppc/phs/>. This web site is a reference source about Direct Access created specifically for the Corps.

***With the fearful strain that is on me day and night,  
if I did not laugh I should die.  
~Abraham Lincoln***



You might be an Engineer If .....

- your significant other hasn't the foggiest idea what you do at work.
- your IQ is higher than your weight.
- your favorite James Bond character is "Q", the guy who makes the gadgets.
- you didn't really need us to explain who "Q" is.
- you think that when the people around you yawn it's because they didn't get enough sleep.
- you have "Dilbert" comics displayed anywhere in your work area.
- you are at an airshow and actually know how fast the skydivers are falling.
- you have used coat hangers and duct tape for something other than hanging coats and taping ducts.



## Hoover Dam Bypass

The Colorado River Bridge is the central portion of the Hoover Dam Bypass Project. Construction on the nearly 2,000 foot long bridge began in late January 2005 and the completion of the entire Hoover Dam Bypass Project is expected in Late 2010. When completed, this signature bridge will span the Black Canyon (about 1,500 feet south of the Hoover Dam), connecting the Arizona and Nevada Approach highways nearly 900-feet above the Colorado River.

These pictures were taken during a helicopter tour over the Dam in October 2009 by a friend of Mark Stafford, NIH. For more pictures and information, please visit the Hoover Dam Bypass website at <http://www.hooverdambypass.org/default.htm> and check out the [What's New](#) and [Construction Activities](#) pages for details on how this project is advancing.



*Construction of arch piers*

A few interesting facts about the Hoover Dam Bypass...

### **Q. DOES THE COLORADO RIVER BRIDGE HAVE A NAME?**

- A. Yes, the United States Congress officially named it the “Mike O’Callaghan-Pat Tillman Memorial Bridge” after two prominent local citizens who dedicated themselves to public service and the greater good. Mike O’Callaghan was a longtime Nevadan, former Governor, community leader, and businessman. He died in March 2004 at the age of 74. Pat Tillman graduated with honors from ASU and played professional football for the Arizona Cardinals before joining the Army. He was killed in Afghanistan in 2004 at the age of 27.

### **Q. WHAT IS THE BUDGET FOR THE HOOVER DAM BYPASS AND WHERE DOES THE MONEY COME FROM?**

- A. The design and construction budget remains unchanged at \$240 million. The Colorado River Bridge construction portion of that budget is \$114 million. The \$240 million budget

*(Continued on page 19)*



consists of \$100 million in federal funds, \$20 million each from the states of Arizona and Nevada, and \$100 million in state bond funds. Of the approximate \$130 million in bond funds (\$100 million plus interest) advanced by the states of Arizona and Nevada, approximately \$96.3 million has been repaid.



*Looking north from downstream of the Hoover Dam*

**Q. HOW MANY PHASES OF CONSTRUCTION HAVE OCCURRED ON THE BYPASS?**

- A. There have been six distinct, yet overlapping, phases of Bypass construction:
- Relocation of portions of the Western Area Power Administration (WAPA) transmission system and switchyard
  - Arizona approach – 2 miles of bypass roadway
  - Nevada approach – 3 miles of bypass roadway
  - Colorado River Bridge
  - Interim surfacing of Bypass
  - Final surfacing and roadway tie-ins

**Q. WHAT ARE SOME KEY FACTS ABOUT THE COLORADO RIVER BRIDGE?**

- The arch span is 1,060 feet long
- The Bridge is 1,900 feet long
- The Bridge deck and sidewalk is located approximately 900 feet above the Colorado River
- The Bridge is located approximately 1,500 feet south of the Hoover Dam



**Q. WILL THERE BE A SIDEWALK ON THE COLORADO RIVER BRIDGE?**

**A.** Yes, it will be located on the north side of the Bridge for optimum viewing of the Hoover Dam. The sidewalk is part of the pedestrian and visitor amenities, which include a parking lot, trail, and interpretive plaza.

**Q. WHO HAS BEEN INVOLVED IN THE PROJECT LEADERSHIP?**

**A.** The Project Management Team (PMT), a multi-agency stakeholder team, oversees the Hoover Dam Bypass Project. The Central Federal Lands Division of the Federal Highway Administration leads the PMT and is responsible for the direct management and oversight of all design and construction activities. Many of the consulting and contracting industries' finest are engaged in this project. The PMT consists of the Arizona and Nevada Departments of Transportation, the U.S. Bureau of Reclamation, the National Park Service, and the Western Area Power Administration.



*Looking southwest from above the Hoover Dam with Lake Mead in the foreground.*



## New Engineer Officers

The EPAC would like to acknowledge the following engineer officers who were commissioned between March and November 2009. The EPAC welcomes each of you and hopes you will enjoy a long and prosperous career in the PHS. To those who are new to the Corps, and even those who have been around for a while, please take some time to review the Welcome Package posted on the Engineers' website,

<http://www.usphsengineers.org/careerdevelopment/EPACWelcomePackage.pdf>.

It contains a prioritized list of tasks new officers should focus their efforts on within the first 30/60/90/120 days after being Called to Active Duty. The Welcome Package is a one-stop shopping tool for information on everything from uniforms to promotion to military benefits.

Rank	Last	First	OPDIV	Location
LT	Beckman	Brandon	IHS	Lakeside, AZ
LCDR	Casey	Martin	CMS	Baltimore, MD
LTJG	Dar	David	FDA	Silver Spring, MD
LCDR	Frazier	Cathie	IHS	Tucson, AZ
LT	Hess	Jacob	IHS	Anchorage, AK
LCDR	Kim	Erin	FDA	Rockville, MD
LTJG	Miller	Griff	EPA	Philadelphia, PA
LT	Murray	Mario	BOP	Memphis, TN
LTJG	Ortega	Cristina	FDA	Silver Spring, MD
LT	O'Shea	Michael	IHS	Anchorage, AK
LT	Schoppert	Shad	IHS	Anchorage, AK
LTJG	Spindel	Samantha	FDA	Silver Spring, MD
LT	Toor	Sadaf	FDA	Silver Spring, MD
LT	VanVleet	Joshua	IHS	Lakeside, AZ
LT	Vaught	Christopher	IHS	Anchorage, AK
LTJG	Wolff	Cody	IHS	Mobridge, SD



Dear Readers,

The *Machinatores Vitae* newsletter is a publication of the EPAC, but we need help in bringing you the stories you want to read. Please consider submitting an article for an upcoming issue or let us know when you or a colleague have reached a milestone, been recognized for an accomplishment, or have an experience to share. If you are an accomplished writer, send something along that is already polished. If you don't feel like a Hemingway or Dickinson, just send enough detail so the writing team can take hold of it and build the story for you.

The writing staff can only see a bit of the big world that is public health engineering. There are numerous accomplishments even within our readership that remain unknown except in the relatively small circles around you. If you have not presented at a national meeting, the likelihood is that no one outside of your agency, or possibly even Office, ever heard about your pet project that you nearly exhausted yourself completing. Here is your chance to shine!

All ideas are welcomed. Remember that we do not have to solely focus on work going on within the PHS. Let us know if you hear of new technologies or applications, or just find an interesting story from the outside world. The rule of thumb is that if you as an engineer are interested in it, then others will be too!

Send your thoughts, suggestions, or a brief synopsis of a proposed article to the newsletter editors at [epac@usphsengineers.org](mailto:epac@usphsengineers.org).

Thank you,

CDR Jen Mosser  
CDR Peter Nachod

The *Machinatores Vitae* is published quarterly and posted on the USPHS Engineer Professional Advisory Committee website. The next issue of the newsletter will be published in March 2010. The deadline for submitting articles is February 15, 2010.

If you have suggestions or comments about the newsletter, or would like to submit an article, please contact the editors at [epac@usphsengineers.org](mailto:epac@usphsengineers.org).

Editor-in-Chief: CDR Jennifer Mosser  
Managing Editor: CDR Peter Nachod  
Copy Editor: CAPT James Ludington