



American Society for Quality (ASQ) — Washington, DC & Maryland Metro Section (509), Software Special Interest Group (SSIG)  
IEEE Computer Society — Washington, DC & Northern Virginia Chapters  
Society for Software Quality (SSQ) — Washington, DC Area Chapter

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## Independent Verification Approaches for FDA's Office of Science and Engineering Laboratories

by: Brian Fitzgerald

Tuesday February 24, 2009

The talk will introduce some of the software related capabilities and independent verification techniques used in the Software Lab for the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) Office of Science and Engineering Laboratories (OSEL). OSEL supports the scientific basis for the FDA regulatory decision-making, developing independent information for regulatory and other public health activities of CDRH. Researchers are involved in mission-oriented science activities including test methods development, risk assessments, forensic investigations, product evaluations, and technology assessment.

The approaches to be discussed, when taken together as a whole, may provide an analog to many of the life science based assay techniques traditionally found in other areas. Projects include researching formal methods as they relate to generalized 'assurance cases' including safety and compliance, and developing forensic techniques for detecting and investigating software failure. Mr. Fitzgerald will outline some of the techniques currently in use and introduce future directions for the Lab.



Mr. Fitzgerald is Deputy Director of the Division of Electrical and Software Engineering within the FDA's CDRH OSEL, specializing in systems, software evaluation, and safety research. He has been instrumental in developing FDA guidance on cybersecurity in medical devices and FDA regulations. He is a member of the AAMI software committee.

Prior to joining FDA, he was an accredited software expert and lead auditor for two European notified bodies. While at Underwriters Laboratories Mr. Fitzgerald helped start their software safety initiative. He continues to conduct seminars in software safety, risk management, 21 CFR Part 11, cybersecurity, software related regulatory affairs and medical quality systems. He is a member of the US National Council of the International Electrotechnical Commission and has contributed to national and international standards: UL 1998, IEC 60601-1-4, AAMI SW68, and IEC 62034. He was nominated as a US National Expert by AAMI to WG22 of IEC SC62a and to ISO TC210 WG1.

Mr. Fitzgerald was educated in England and received an engineering degree from University College Cardiff in Wales.

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**6:30 PM – Networking and Pizza(\*)**

**7:00 - 8:00 PM – Program**

(\*) - *There is no cost to attend at McLean and Silver Spring.*

## Locations:

The meeting will be held at three locations using video tele-conferencing (VTC).  
The presentation will originate from FDA, Silver Spring, MD.

MITRE, room 1N100  
7515 Colshire Drive  
McLean, VA 22102

FDA, Bld 22, room 1311  
White Oak Campus  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

MITRE, room 1002  
260 Industrial Way West  
Eatontown, NJ 07724

MITRE, room 1M306  
202 Burlington Rd (Rt. 62)  
Bedford, MA 01730

*If you can host another location via VTC, please contact Scott Ankrum (below)*

## Registration:

*If you cannot attend at any location, select telephone dial-in when you register.*

*To RSVP for FDA (Silver Spring), please indicate citizenship. If not a US citizen, please provide your title, employer, and address. Allow two business days for registration before the meeting.*

*You must register by noon on Monday, February 23.*

Registration Website: <http://www.asq509.org/ht/d/DoSurvey/i/26913>

For registration problems or further information contact Scott Ankrum at: <a href="mailto:ankrums@mitre.org">ankrums@mitre.org</a> or 703-983-6127
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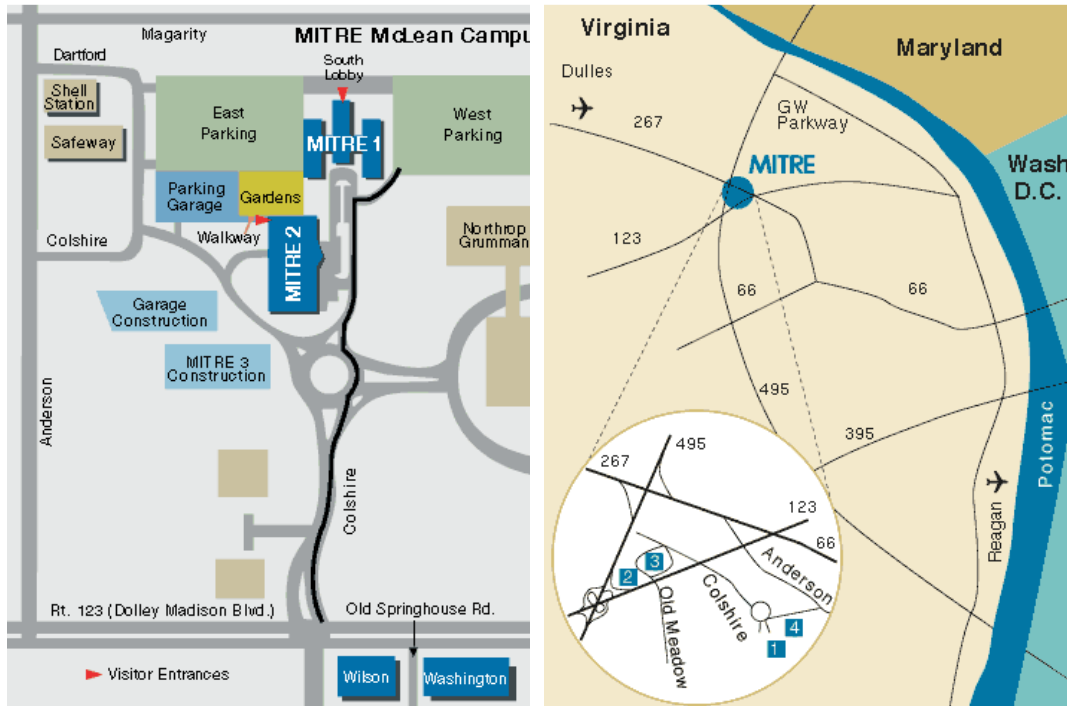
**Software SIG Chairman:** T. Scott Ankrum (ASQ & IEEE)  
**Software SIG Committee:** John Blyskal (IEEE); Richard Eng (ASQ); Chris Jones (ASQ & SSQ); Alfred Kromholz (SSQ); Tim Rice; James M. Simpson (ASQ); Tom Starai (IEEE)

**Sponsored Jointly By:** The American Society for Quality (ASQ), Washington DC & Maryland Metro Section (509), Software Special Interest Group (SSIG); IEEE Computer Society, Washington, DC & Northern Virginia Chapters; and Society for Software Quality (SSQ), Washington, DC Area Chapter.

Members of the **ASQ SSIG** include software quality professionals, software engineers, and others interested in applying quality principles to the field of software development. See our web page: <http://www.asq509.org/ht/d/sp/i/2499/pid/2499>. We meet every month, usually at the MITRE facility in Tyson's Corner, Virginia, with VTC to other locations.

**Directions to the MITRE Facility in McLean, Virginia:**

Take the Beltway, I-495 to Virginia. Take Exit 46B (McLean, Route 123). Take Route 123 North, (also called Dolley Madison Blvd.) and go to the second traffic light at Colshire Drive. Turn right on Colshire Drive and continue through circle on Colshire. **Park in front of or to the right of the buildings, before passing the gate. (The gates are closed at 7:00).** Additional directions can be found at: [http://www.mitre.org/about/locations/mitre1\\_map.html](http://www.mitre.org/about/locations/mitre1_map.html)



**Directions to the FDA facility in Silver Spring, MD:**

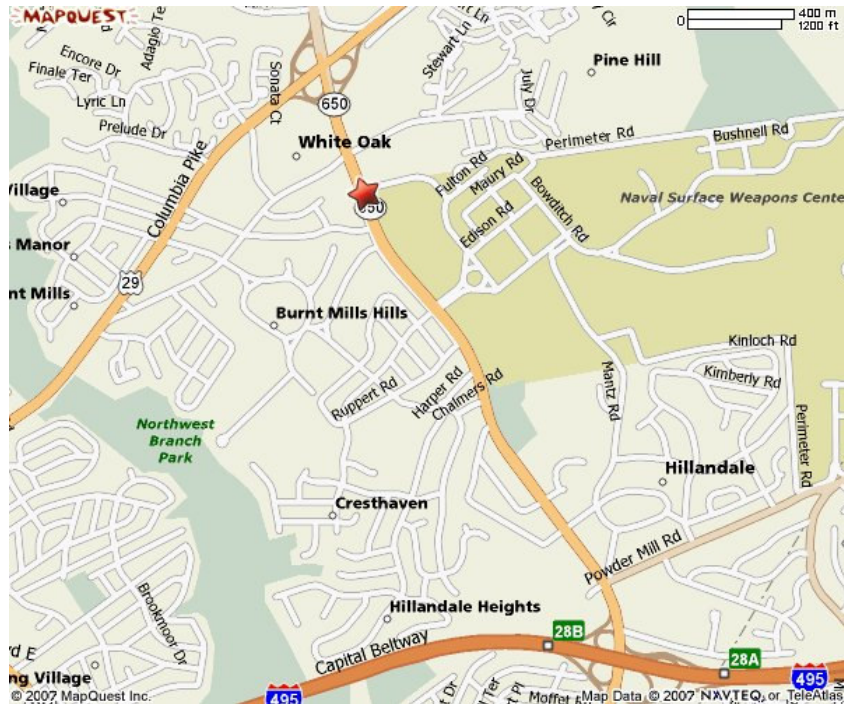
**From the Capital Beltway, I-495,** take New Hampshire Ave, Rt 650 north to Michelson Rd.

**From Columbia Pike, Rt 29,** take New Hampshire Ave, Rt 650 south to Michelson Rd

Due to construction, all traffic must use the Michelson Rd entrance. Follow signs to visitor parking.

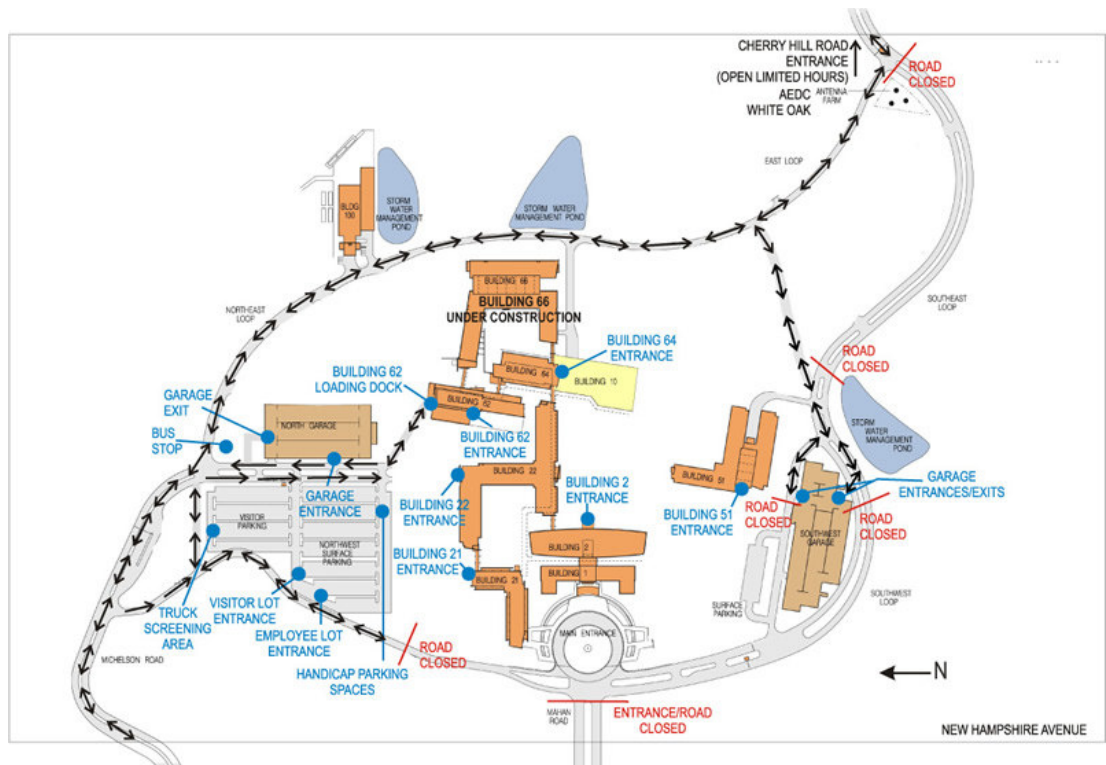
**From the Capital Beltway, I-495,** take New Hampshire Ave, Rt 650 north to Michelson Rd.

**From Columbia Pike, Rt 29,** take New Hampshire Ave, Rt 650 south to Michelson Rd



Due to construction, all traffic must use the Michelson Rd entrance. Follow signs to visitor parking.

Enter building 22.

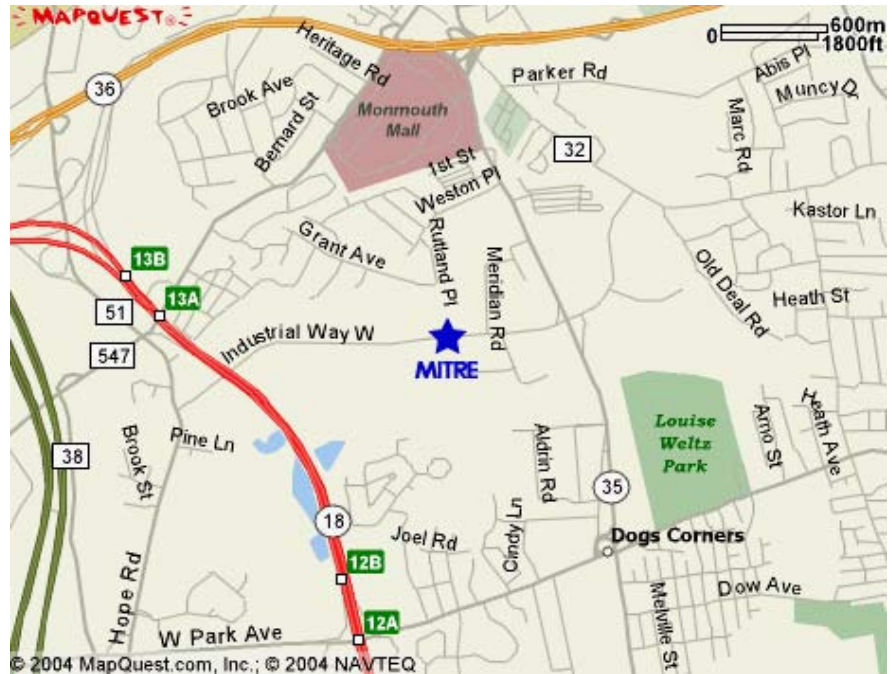




## Directions to the MITRE Facility in Eatontown, New Jersey:

### From the New Jersey Turnpike

If traveling from the **SOUTH**, get off the Turnpike at Exit 7A (195 toward Shore Points). Take 195 East towards the ocean and shortly after 195 turns into Route 138 (approximately 35 miles) watch for Route 18 North (Eatontown). Take Route 18 North to Exit 13A (Wayside West/Wyckoff Road). At end of ramp, bear left. At first traffic light (Hope Road) make a left turn. Make second left turn onto Industrial Way. The MITRE Corporation is next to the First Atlantic Credit Union on the left hand side of Industrial Way. There is a MITRE sign out front.



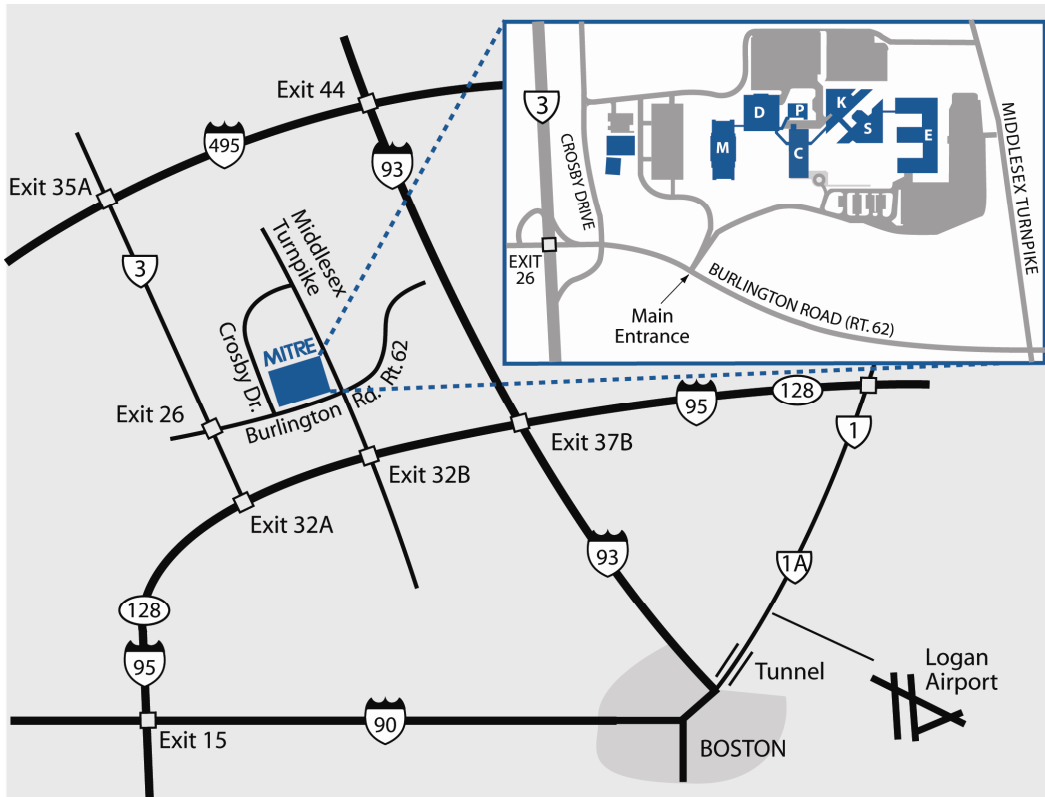
There are two buildings on the left side of Industrial Way. The first building is MITRE, the second building is TYCO. Take a left turn into the parking lot of the first building, which is MITRE.

If traveling from the **NORTH**, get off the Turnpike at Exit 11 (Garden State parkway exit). Follow the Garden State Parkway until Exit 105 (Eatontown). Follow the directions from the Garden State Parkway below.

**From the Garden State Parkway:** Follow the Garden State Parkway from the North or from the South to Exit 105 (the exit numbers increase going from south to north). After paying the toll at Exit 105, make first right turn onto Hope Road. Follow Hope Road to Industrial Way (second left turn after crossing Wyckoff/Shafto Road). Make second left turn onto Industrial Way. The MITRE Corporation is next to the First Atlantic Credit Union on the left hand side of Industrial Way. There is a MITRE sign out front. There are two white buildings on the left side of Industrial Way. The first building is MITRE, the second building is TYCO. Take a left turn into the parking lot of the first building, which is MITRE.

**When you are facing the front of the MITRE building, the entrance to the ASQ meeting will be from the left parking lot opposite First Atlantic bank. Follow the signs to the conference room.**

## Directions to the MITRE complex in Bedford, Massachusetts:



### From New Hampshire to MITRE Complex:

Take Route 3 South to Exit 26 (Route 62)

Turn Left on Route 62. It is a short distance to the MITRE entrance on left--watch for building directories on MITRE grounds

### From Manchester Airport (NH) to MITRE Complex:

Start out going West on Airport Rd. toward parking

Turn slight right onto Brown Ave/NH-3A

Merge onto NH-101 West via the ramp on the left toward Bedford/Nashua

Take the Everett Turnpike South exit toward Merrimack/Nashua

Merge onto Everett Turnpike (toll road)

Everett Turnpike becomes US-3 South

Take exit 26 (Route 62) toward Bedford/Burlington

Turn Left onto (Route 62) Burlington Road

At second set of traffic lights, turn left at MITRE Bedford Campus entrance--watch for building directories on MITRE grounds.

### Logan Airport to MITRE Complex:

Exit airport towards Route 1A South/Sumner Tunnel (I-93) Boston.

Proceed through tunnel towards Storrow Drive (I-93 North).

Take I-93 North eleven miles to Exit 37B (Route 128 (I-95) South).

Take Route 128 (I-95) South six miles to Exit 32A.

Take Exit 32A, and proceed on Route 3 North.

Take Route 3 North for two miles to Exit 26 (Route 62).

Bear right on Route 62.

Take Route 62 a short distance to the MITRE Bedford Campus entrance on left--watch for building directories on MITRE grounds.