## ArevaEPRDCDocsPEm Resource

**From:** Wunder, George
**Sent:** Wednesday, July 02, 2014 4:26 PM
**To:** HOTTLE Nathan (AREVA)
**Cc:** ArevaEPRDCDocsPEm Resource
**Subject:** RE: EPR eRAI report
**Attachments:** 0208_eRAI_Question_Status.pdf

Nathan,

Attached please find the requested report.

Thanks,

George

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**From:** HOTTLE Nathan (AREVA) [mailto:Nathan.Hottle@areva.com]
**Sent:** Wednesday, July 02, 2014 4:06 PM
**To:** Wunder, George
**Subject:** EPR eRAI report

George – Can you send me another report from the eRAI database. I don't expect that there have been a lot of changes, but it helps us to try to keep the books aligned. The attached file is what you sent last time and was exactly what I needed. Thanks.

*Nathan Hottle*
AREVA Inc.
3315 Old Forest Road
Lynchburg, VA 24501
Phone 434-832-3864
Mobile 434-485-4239
nathan.hottle@areva.com

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**From:** Wunder, George [mailto:George.Wunder@nrc.gov]
**Sent:** Tuesday, April 01, 2014 12:00 PM
**To:** HOTTLE Nathan (EP/PE)
**Cc:** ArevaEPRDCDocsPEm Resource
**Subject:** RE: EPR Open Item Report 12_3_13

Nathan,

Attached please find the report you requested.

Thanks,

George

**From:** HOTTLE Nathan (AREVA) [mailto:Nathan.Hottle@areva.com]
**Sent:** Monday, March 31, 2014 10:00 AM
**To:** Wunder, George
**Subject:** FW: EPR Open Item Report 12_3_13

George – When you get a chance, a report similar to this eRAI report that John Segala provided in December would be very helpful for me. Thanks.

*Nathan Hottle*
AREVA Inc.
3315 Old Forest Road
Lynchburg, VA 24501
Phone 434-832-3864
Mobile 434-485-4239
nathan.hottle@areva.com

**From:** Segala, John [mailto:John.Segala@nrc.gov]
**Sent:** Tuesday, December 03, 2013 12:29 PM
**To:** HOTTLE Nathan (EP/PE)
**Cc:** Miernicki, Michael
**Subject:** EPR Open Item Report 12_3_13

**Hearing Identifier:** AREVA_EPR_DC_Docs_Public
**Email Number:** 180

**Mail Envelope Properties** (DAC719623E968245BD52D03696111100021E1C7603C2)

**Subject:** RE: EPR eRAI report
**Sent Date:** 7/2/2014 4:25:42 PM
**Received Date:** 7/2/2014 4:25:44 PM
**From:** Wunder, George

**Created By:** George.Wunder@nrc.gov

**Recipients:**
"ArevaEPRDCDocsPEm Resource" <ArevaEPRDCDocsPEm.Resource@nrc.gov>
Tracking Status: None
"HOTTLE Nathan (AREVA)" <Nathan.Hottle@areva.com>
Tracking Status: None

**Post Office:** HQCLSTR02.nrc.gov

| **Files** | **Size** | **Date & Time** |
|---|---|---|
| MESSAGE | 1773 | 7/2/2014 4:25:44 PM |
| 0208_eRAI_Question_Status.pdf | 987273 | |

**Options**
**Priority:** Standard
**Return Notification:** No
**Reply Requested:** No
**Sensitivity:** Normal
**Expiration Date:**
**Recipients Received:**

# eRAI Question Status Report
# For use by Project Manager

**Docket(s):**
**52-020-U. S. EPR Standard Design Certification - Docket Number 52-020**

**Chapter(s):,01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19**

**Technical Branch(s):Advanced Reactor Branch 1 (ARB1),Advanced Reactor Branch 2 (ARB2),AP1000 Projects Branch 1 (NWE1),Balance of Plant & Fire Protection Branch (BPFP),Balance of Plant and Technical Specifications Branch (BPTS),Balance of Plant Branch 1 (AP1000/EPR Projects) (SBPA),Balance of Plant Branch 1 (SBPA),Balance of Plant Branch 2 (ESBWR/ABWR) (SBPB),Balance of Plant Branch 2 (SBPB),Component Integrity Branch (CIB),Component Integrity, Performance, and Testing Branch 1 (AP1000/EPR Projects) (CIB1),Component Integrity, Performance, and Testing Branch 2 (ESBWR/ABWR Projects) (CIB2),Construction Inspection and Allegations Branch (CCIB),Construction Mechanical Vendor Branch (CMVB),Containment & Ventilation Branch (SCVB),Containment and Ventilation Branch 1 (AP1000/EPR Projects) (SPCV),Containment and Ventilation Branch 2 (ESBWR/ABWR Projects) (SBCV),Dose Assessment Team (RPAC/RDAT),Electrical Engineering Branch (EEB),Engineering Mechanics Branch (EMB),Engineering Mechanics Branch 1 (AP1000/EPR Projects) (EMB1),Engineering Mechanics Branch 2 (ESBWR/ABWR Projects) (EMB2),Environmental Projects Branch 1 (EPB1),Environmental Projects Branch 1 (RAP1),Environmental Projects Branch 2 (EPB2),Environmental Projects Branch 2 (RAP2),Environmental Projects Branch 3 (RAP3),Environmental Technical Support Branch (RENV),EPR Projects Branch (NARP),ESBWR/ABWR Projects 1 (NGE1),ESBWR/ABWR Projects 2 (NGE2),Financial, Policy, & Rulemaking Branch (NRR/DPR/PFPB),Fire Protection Team (SFPT),Geosciences and Geotechnical Engineering Branch 1 (RGS1),Geosciences and Geotechnical Engineering Branch 2 (RGS2),Health Physics Branch (CHPB),Hydrologic Engineering Branch (RHEB),Hydrology & Meteorology Branch (RHMB),I&C and Electrical Engineering Branch (ICE),Instrumentation and Controls Branch (ICB),Instrumentation, Controls and Electrical Engineering 1 (AP1000/EPR Projects) (ICE1),Instrumentation, Controls and Electrical Engineering 2 (ESBWR/ABWR Projects) (ICE2),Integrated Security Coordination and Policy Branch (NSIR/DSP/ISCPB),ITAAC Branch (CITB),Licensing and Inspection Branch (NSIR/DPR/LIB) (EP),Licensing Branch 1 (LB1),Licensing Branch 2 (LB2),Licensing Branch 3 (LB3),Licensing Branch 4 (LB4),Materials and Chemical Engineering Branch (MCB),Mechanical Engineering Branch (MEB),Operating Licensing and Human Performance Branch (AP1000/EPR Projects) (COLP),Operator Licensing & Human Performance Branch (COLP),PRA & Severe Accidents Branch (SPRA),PRA and Severe Accidents Branch (SPRA),PRA Licensing, Operations Support and Maintenance Branch 1 (AP1000/EPR Projects) (SPLA),PRA Licensing, Operations Support and Maintenance Branch 2 (ESBWR/ABWR Projects) (SPLB),Quality and Vendor Branch 1 (AP1000/EPR Projects) (CQVP),Quality and Vendor Branch 2 (ESBWR/ABWR) (CQVB),Quality Assurance Branch (CQAB),Radiation Protection & Accident Consequences Branch (RPAC),Reactor Security and Programs Branch (NSIR/DRP/RSPLB),Reactor Security Rulemaking and Licensing Branch (NSIR/DSP/RSRLB),Reactor System, Nuclear Performance and Code Review (SRSB),Security Program Support Branch (NSIR/DSP/SPSB),Siting and Accident Conseq Branch (RSAC),Structural Engineering Branch 1 (AP1000/EPR Projects) (SEB1),Structural Engineering Branch 1 (SEB1),Structural Engineering Branch 2 (ESBWR/ABWR Projects) (SEB2),Structural Engineering Branch 2 (SEB2),Technical Specification Branch (CTSB),Test Branch,USAPWR Projects Branch (NMIP)**

**Question Status: Confirmatory Action,In Evaluation,Issued/Waiting for Response,NRC Concurred,Pending Review,Resolved - Closed,Reviewed Chapter PM,Reviewed LBC,Reviewed OGC,Reviewed TBC,Unresolved - Closed**

**Question Type: Open Items**

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| **52-020-U. S. EPR Standard Design Certification - Docket Number 52-020 Total - 724 Question(s) / 774 Response(s)** | | | | | | | | | |
| **Chapter 02 Total - 23 Question(s) / 24 Response(s)** | | | | | | | | | |
| 256 | 2937 | 02.03.01-13 | Harvey, Brad | 7/7/2009 | ML092050754 | 5/4/2010 | ML101250005 | Yes | Unresolved - Closed |
| 256 | 2937 | 02.03.01-14 | Harvey, Brad | 7/7/2009 | ML092050754 | 3/3/2011 | ML110620323 | Yes | Resolved - Closed |
| 256 | 2937 | 02.03.01-15 | Harvey, Brad | 7/7/2009 | ML092050754 | 2/26/2010 | ML100600272 | Yes | Unresolved - Closed |
| 288 | 3634 | 02.03.01-16 | Harvey, Brad | 8/27/2009 | ML092400278 | 4/1/2010 | ML100910400 | Yes | Resolved - Closed |
| 453 | 5109 | 02.03.01-17 | Harvey, Brad | 10/25/2010 | ML103090064 | 12/16/2010 | ML103550015 | Yes | Resolved - Closed |
| 453 | 5109 | 02.03.01-18 | Harvey, Brad | 10/25/2010 | ML103090064 | 12/16/2010 | ML103550015 | Yes | Resolved - Closed |
| 453 | 5109 | 02.03.01-19 | Harvey, Brad | 10/25/2010 | ML103090064 | 12/16/2010 | ML103550015 | Yes | Resolved - Closed |
| 453 | 5110 | 02.03.04-10 | Harvey, Brad | 10/25/2010 | ML103090064 | 2/23/2011 | ML110560374 | Yes | Resolved - Closed |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 453 | 5110 | 02.03.04-11 | Harvey, Brad | 10/25/2010 | ML103090064 | 1/28/2011 | ML110280318 | Yes | Resolved - Closed |
| 453 | 5110 | 02.03.04-12 | Harvey, Brad | 10/25/2010 | ML103090064 | 1/28/2011 | ML110280318 | Yes | Resolved - Closed |
| 453 | 5110 | 02.03.04-13 | Harvey, Brad | 10/25/2010 | ML103090064 | 12/16/2010 | ML103550015 | Yes | Resolved - Closed |
| 256 | 2938 | 02.03.04-7 | Harvey, Brad | 7/7/2009 | ML092050754 | 2/26/2010 | ML100600272 | Yes | Unresolved - Closed |
| 256 | 2938 | 02.03.04-8 | Harvey, Brad | 7/7/2009 | ML092050754 | 2/26/2010 | ML100600272 | Yes | Unresolved - Closed |
| 288 | 3649 | 02.03.04-9 | Harvey, Brad | 8/27/2009 | ML092400278 | 2/26/2010 | ML100570355 | Yes | Resolved - Closed |
| 256 | 2940 | 02.03.05-6 | Harvey, Brad | 7/7/2009 | ML092050754 | 4/20/2010 | ML101100866 | Yes | Resolved - Closed |
| 256 | 2940 | 02.03.05-7 | Harvey, Brad | 7/7/2009 | ML092050754 | 4/20/2010 | ML101100866 | Yes | Resolved - Closed |
| 288 | 3650 | 02.03.05-8 | Harvey, Brad | 8/27/2009 | ML092400278 | 2/26/2010 | ML100570355 | Yes | Resolved - Closed |
| 453 | 5111 | 02.03.05-9 | Harvey, Brad | 10/25/2010 | ML103090064 | 2/23/2011 | ML110560374 | Yes | Resolved - Closed |
| 35 | 527 | 02.05.04-2 | Wang, Weijun | 7/11/2008 | ML082240620 | 7/8/2011 | ML11192A067 | Yes | Unresolved - Closed |
| 261 | 3330 | 02.05.04-4 | Wang, Weijun | 7/17/2009 | ML092050755 | 2/10/2011 | ML110420517 | Yes | Resolved - Closed |
| 274 | 3521 | 02-1 | Patel 02_13_2012 # 561550, Jay | 8/12/2009 | ML092330940 | 4/1/2010 | ML100910397 | Yes | Resolved - Closed |
| 288 | 3640 | 02-2 | Patel 02_13_2012 # 561550, Jay | 8/27/2009 | ML092400278 | 4/1/2010 | ML100910400 | Yes | Resolved - Closed |
| 541 | 6322 | 02-3 | Harvey, Brad | 3/2/2012 | ML12115A287 | 12/18/2013 | ML14014A207 | Yes | In Evaluation |
| 541 | 6322 | 02-3 | Harvey, Brad | 3/2/2012 | ML12115A287 | 9/5/2013 | ML13252A257 | Yes | In Evaluation |
| **Chapter 03 Total - 109 Question(s) / 118 Response(s)** | | | | | | | | | |
| 420 | 4687 | 03.02.01-12 | McNally, Richard | 6/15/2010 | ML102380583 | 6/19/2013 | ML13170A583 | Yes | Resolved - Closed |
| 420 | 4687 | 03.02.01-15 | McNally, Richard | 6/15/2010 | ML102380583 | 4/13/2011 | ML111030638 | Yes | Resolved - Closed |
| 510 | 6026 | 03.02.01-19 | McNally, Richard | 8/31/2011 | ML11285A034 | 4/4/2012 | ML12095A305 | Yes | Resolved - Closed |
| 420 | 4661 | 03.02.02-11 | McNally, Richard | 6/15/2010 | ML102380583 | 6/30/2011 | ML11181A264 | Yes | Resolved - Closed |
| 435 | 4831 | 03.02.02-12 | McNally, Richard | 8/10/2010 | ML102610006 | 11/29/2010 | ML103360536 | Yes | Unresolved - Closed |
| 504 | 5982 | 03.02.02-14 | McNally, Richard | 8/12/2011 | ML11242A181 | 5/9/2012 | ML12130A091 | Yes | Resolved - Closed |
| 567 | 6945 | 03.02.02-15 | McNally, Richard | 12/11/2012 | ML12346A468 | 3/18/2013 | ML13078A061 | Yes | Resolved - Closed |
| 576 | 7010 | 03.02.02-16 | Ahmed, Sardar | 2/28/2013 | ML13059A049 | 7/25/2013 | ML13206A405 | Yes | Resolved - Closed |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 72 | 1061 | 03.02.02-6 | McNally, Richard | 9/9/2008 | ML083010217 | 11/14/2008 | ML083190852 | Yes | Resolved - Closed |
| 420 | 4661 | 03.02.02-7 | McNally, Richard | 6/15/2010 | ML102380583 | 6/19/2013 | ML13170A583 | Yes | Resolved - Closed |
| 420 | 4661 | 03.02.02-8 | McNally, Richard | 6/15/2010 | ML102380583 | 6/30/2011 | ML11181A264 | Yes | Resolved - Closed |
| 508 | 6005 | 03.03.01-5 | Chakravorty, Manas | 8/22/2011 | | 1/27/2012 | ML12027A212 | Yes | Resolved - Closed |
| 109 | 1523 | 03.04.01-1 | Li, Chang | 10/20/2008 | ML083190564 | 12/15/2008 | ML083500586 | Yes | Resolved - Closed |
| 377 | 4472 | 03.04.01-13 | Li, Chang | 3/11/2010 | ML101470949 | 4/9/2010 | ML101020003 | Yes | Resolved - Closed |
| 435 | 4981 | 03.04.01-14 | Li, Chang | 8/10/2010 | ML102610006 | 11/29/2010 | ML103360536 | Yes | Resolved - Closed |
| 109 | 1524 | 03.04.01-2 | Li, Chang | 10/20/2008 | ML083190564 | 12/15/2008 | ML083500586 | Yes | Resolved - Closed |
| 118 | 1519 | 03.04.01-4 | Li, Chang | 10/22/2008 | ML083110193 | 12/1/2008 | ML083380092 | Yes | Resolved - Closed |
| 118 | 1519 | 03.04.01-5 | Li, Chang | 10/22/2008 | ML083110193 | 12/1/2008 | ML083380092 | Yes | Resolved - Closed |
| 118 | 1519 | 03.04.01-6 | Li, Chang | 10/22/2008 | ML083110193 | 12/1/2008 | ML083380092 | Yes | Resolved - Closed |
| 533 | 6224 | 03.06.01-13 | Hernandez, Raul | 12/8/2011 | ML12018A015 | 3/22/2012 | ML12251A358 | Yes | Resolved - Closed |
| 547 | 6499 | 03.06.01-14 | Miernicki, Michael | 5/16/2012 | ML12167A002 | 2/1/2013 | ML13065A116 | Yes | Resolved - Closed |
| 547 | 6499 | 03.06.01-14 | Miernicki, Michael | 5/16/2012 | ML12167A002 | 4/11/2013 | ML13121A411 | Yes | Resolved - Closed |
| 354 | 4220 | 03.06.02-35 | Li, Yueh-Li | 1/8/2010 | ML100750324 | 7/29/2013 | ML13211A032 | Yes | Confirmatory Action |
| 354 | 4220 | 03.06.02-35 | Li, Yueh-Li | 1/8/2010 | ML100750324 | 12/19/2013 | ML14014A203 | Yes | Confirmatory Action |
| 48 | 888 | 03.06.03-10 | Reichelt, Eric | 8/6/2008 | ML082341032 | 11/7/2008 | ML083170596 | Yes | Resolved - Closed |
| 48 | 888 | 03.06.03-11 | Reichelt, Eric | 8/6/2008 | ML082341032 | 9/18/2008 | ML082680040 | Yes | Resolved - Closed |
| 48 | 888 | 03.06.03-12 | Reichelt, Eric | 8/6/2008 | ML082341032 | 11/7/2008 | ML083170596 | Yes | Resolved - Closed |
| 48 | 888 | 03.06.03-13 | Reichelt, Eric | 8/6/2008 | ML082341032 | 11/7/2008 | ML083170596 | Yes | Resolved - Closed |
| 48 | 889 | 03.06.03-14 | Reichelt, Eric | 8/6/2008 | ML082341032 | 9/18/2008 | ML082680040 | Yes | Resolved - Closed |
| 467 | 5333 | 03.06.03-28 | Reichelt, Eric | 1/5/2011 | ML110260478 | 2/17/2012 | ML12048B458 | Yes | Resolved - Closed |
| 370 | 4292 | 03.07.01-27 | Chakravorty, Manas | 2/18/2010 | ML100840514 | 1/17/2013 | ML13065A072 | Yes | Resolved - Closed |
| 370 | 4292 | 03.07.01-27 | Chakravorty, Manas | 2/18/2010 | ML100840514 | 3/19/2013 | ML13078A422 | Yes | Resolved - Closed |
| 370 | 4292 | 03.07.01-27 | Chakravorty, Manas | 2/18/2010 | ML100840514 | 2/5/2013 | ML13065A126 | Yes | Resolved - Closed |
| 370 | 4272 | 03.07.02-64 | Chakravorty, Manas | 2/18/2010 | ML100840514 | 5/17/2013 | ML13137A485 | Yes | Unresolved - Closed |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 370 | 4272 | 03.07.02-64 | Chakravorty, Manas | 2/18/2010 | ML100840514 | 8/16/2013 | ML13231A120 | Yes | Unresolved - Closed |
| 371 | 4271 | 03.07.02-66 | Xu, Jim | 2/25/2010 | ML100840550 | 12/19/2011 | ML11354A352 | Yes | Resolved - Closed |
| 371 | 4271 | 03.07.02-67 | Xu, Jim | 2/25/2010 | ML100840550 | 9/13/2011 | ML11256A328 | Yes | Unresolved - Closed |
| 489 | 5802 | 03.07.02-75 | Thomas, George | 5/16/2011 | | 1/31/2013 | ML13065A111 | Yes | Confirmatory Action |
| 547 | 6359 | 03.07.02-76 | Thomas, George | 5/16/2012 | ML12167A002 | 11/29/2012 | ML12334A809 | Yes | Resolved - Closed |
| 547 | 6359 | 03.07.02-77 | Thomas, George | 5/16/2012 | ML12167A002 | 10/4/2012 | ML12278A408 | Yes | Resolved - Closed |
| 547 | 6359 | 03.07.02-78 | Thomas, George | 5/16/2012 | ML12167A002 | | | Yes | Resolved - Closed |
| 587 | 7156 | 03.07.02-79 | Thomas, George | 6/25/2013 | | 9/30/2013 | ML13282A484 | Yes | Confirmatory Action |
| 587 | 7156 | 03.07.02-79 | Thomas, George | 6/25/2013 | | 1/27/2014 | ML14027A559 | Yes | Confirmatory Action |
| 629 | 7429 | 03.07.02-80 | Park, Sunwoo | 3/6/2014 | ML14065A573 | | | Yes | Issued/Waiting for Response |
| 508 | 6000 | 03.07.03-41 | Thomas, George | 8/22/2011 | | 1/6/2012 | ML12013A045 | Yes | Resolved - Closed |
| 381 | 4421 | 03.07.04-6 | Li, Yong | 3/18/2010 | ML101110011 | 8/13/2010 | ML102250324 | Yes | Resolved - Closed |
| 400 | 4708 | 03.07.04-7 | Tabatabai, Sarah | 5/5/2010 | ML101460285 | 6/24/2010 | ML101760542 | Yes | Resolved - Closed |
| 155 | 1831 | 03.08.01-24 | Xu, Jim | 12/12/2008 | ML090140134 | 5/8/2014 | ML14128A469 | Yes | Issued/Waiting for Response |
| 306 | 3787 | 03.08.01-39 | Thomas, George | 10/9/2009 | ML093080395 | 7/15/2011 | ML11196A206 | Yes | Resolved - Closed |
| 306 | 3787 | 03.08.01-40 | Thomas, George | 10/9/2009 | ML093080395 | 3/11/2010 | ML100700611 | Yes | Issued/Waiting for Response |
| 583 | 7087 | 03.08.03-25 | Scarbrough, Thomas | 5/2/2013 | ML13122A256 | 3/10/2014 | ML14141A299 | Yes | Confirmatory Action |
| 588 | 7157 | 03.08.03-26 | Thomas, George | 6/18/2013 | | 7/29/2013 | ML13211A027 | Yes | Confirmatory Action |
| 445 | 5083 | 03.08.04-15 | Thomas, George | 9/15/2010 | ML102740164 | 7/23/2013 | ML13205A040 | Yes | Confirmatory Action |
| 445 | 5083 | 03.08.04-17 | Thomas, George | 9/15/2010 | ML102740164 | 7/8/2011 | ML11192A007 | Yes | Confirmatory Action |
| 445 | 5083 | 03.08.04-17 | Thomas, George | 9/15/2010 | ML102740164 | 6/27/2013 | ML13183A143 | Yes | Confirmatory Action |
| 445 | 5083 | 03.08.04-19 | Thomas, George | 9/15/2010 | ML102740164 | 7/12/2013 | ML13196A058 | Yes | Confirmatory Action |
| 445 | 5083 | 03.08.04-20 | Thomas, George | 9/15/2010 | ML102740164 | | | Yes | Issued/Waiting for Response |
| 445 | 5083 | 03.08.04-21 | Thomas, George | 9/15/2010 | ML102740164 | 7/23/2013 | ML13205A044 | Yes | Issued/Waiting for Response |
| 445 | 5083 | 03.08.04-26 | Thomas, George | 9/15/2010 | ML102740164 | 7/8/2011 | ML11192A007 | Yes | Confirmatory Action |
| 445 | 5083 | 03.08.04-26 | Thomas, George | 9/15/2010 | ML102740164 | 6/13/2013 | ML13168A005 | Yes | Confirmatory Action |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 445 | 5083 | 03.08.04-27 | Thomas, George | 9/15/2010 | ML102740164 | | | Yes | Confirmatory Action |
| 580 | 7057 | 03.08.04-28 | Thomas, George | 4/4/2013 | ML13077A430 | | | Yes | Issued/Waiting for Response |
| 580 | 7057 | 03.08.04-29 | Thomas, George | 4/4/2013 | ML13077A430 | | | Yes | Issued/Waiting for Response |
| 580 | 7057 | 03.08.04-30 | Thomas, George | 4/4/2013 | ML13077A430 | 8/30/2013 | ML13247A797 | Yes | Resolved - Closed |
| 589 | 7169 | 03.08.04-31 | Thomas, George | 8/1/2013 | | | | Yes | Issued/Waiting for Response |
| 155 | 1833 | 03.08.04-6 | Xu, Jim | 12/12/2008 | ML090140134 | 5/8/2014 | ML14128A469 | Yes | In Evaluation |
| 376 | 4377 | 03.08.05-28 | Thomas, George | 3/11/2010 | ML100840556 | 1/5/2012 | ML12013A042 | Yes | Unresolved - Closed |
| 376 | 4377 | 03.08.05-31 | Thomas, George | 3/11/2010 | ML100840556 | | | Yes | Issued/Waiting for Response |
| 404 | 4692 | 03.09.01-10 | Wu, Cheng-Ih | 5/11/2010 | ML101520140 | 7/30/2010 | ML102110588 | Yes | Resolved - Closed |
| 404 | 4692 | 03.09.01-11 | Wu, Cheng-Ih | 5/11/2010 | ML101520140 | 7/30/2010 | ML102110588 | Yes | Resolved - Closed |
| 404 | 4692 | 03.09.01-12 | Wu, Cheng-Ih | 5/11/2010 | ML101520140 | 7/30/2010 | ML102110588 | Yes | Resolved - Closed |
| 458 | 5149 | 03.09.01-13 | Wu, Cheng-Ih | 10/29/2010 | ML103090037 | 5/26/2011 | ML11147A000 | Yes | Resolved - Closed |
| 458 | 5149 | 03.09.01-14 | Wu, Cheng-Ih | 10/29/2010 | ML103090037 | 5/26/2011 | ML11147A000 | Yes | Resolved - Closed |
| 458 | 5149 | 03.09.01-15 | Wu, Cheng-Ih | 10/29/2010 | ML103090037 | 5/26/2011 | ML11147A000 | Yes | Resolved - Closed |
| 179 | 1938 | 03.09.01-2 | Wu, Cheng-Ih | 1/19/2009 | ML090280602 | 5/13/2009 | ML091350077 | Yes | Resolved - Closed |
| 404 | 4692 | 03.09.01-5 | Wu, Cheng-Ih | 5/11/2010 | ML101520140 | 7/30/2010 | ML102110588 | Yes | Resolved - Closed |
| 404 | 4692 | 03.09.01-6 | Wu, Cheng-Ih | 5/11/2010 | ML101520140 | 7/30/2010 | ML102110588 | Yes | Resolved - Closed |
| 404 | 4692 | 03.09.01-7 | Wu, Cheng-Ih | 5/11/2010 | ML101520140 | 7/30/2010 | ML102110588 | Yes | Resolved - Closed |
| 404 | 4692 | 03.09.01-8 | Wu, Cheng-Ih | 5/11/2010 | ML101520140 | 7/30/2010 | ML102110588 | Yes | Resolved - Closed |
| 404 | 4692 | 03.09.01-9 | Wu, Cheng-Ih | 5/11/2010 | ML101520140 | 7/30/2010 | ML102110588 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-100 | Wong, Yuken | 6/15/2010 | ML102150428 | 8/3/2011 | ML11277A232 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-101 | Wong, Yuken | 6/15/2010 | ML102150428 | 8/3/2011 | ML11277A232 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-103 | Wong, Yuken | 6/15/2010 | ML102150428 | 1/13/2012 | ML12016A013 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-104 | Wong, Yuken | 6/15/2010 | ML102150428 | 10/18/2011 | ML120250223 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-107 | Wong, Yuken | 6/15/2010 | ML102150428 | 1/13/2012 | ML12016A013 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-108 | Wong, Yuken | 6/15/2010 | ML102150428 | 3/22/2012 | ML12251A361 | Yes | Resolved - Closed |

# eRAI Question Status Report
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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 422 | 4792 | 03.09.02-112 | Wong, Yuken | 6/15/2010 | ML102150428 | 8/3/2011 | ML11277A232 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-114 | Wong, Yuken | 6/15/2010 | ML102150428 | 1/13/2012 | ML12016A013 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-119 | Wong, Yuken | 6/15/2010 | ML102150428 | 1/13/2012 | ML12016A013 | Yes | Resolved - Closed |
| 467 | 5344 | 03.09.02-161 | Wong, Yuken | 1/5/2011 | ML110260478 | 3/7/2012 | ML12067A328 | Yes | Resolved - Closed |
| 503 | 5929 | 03.09.02-168 | Wong, Yuken | 7/29/2011 | ML12251A368 | 3/9/2012 | ML12069A403 | Yes | Resolved - Closed |
| 508 | 5994 | 03.09.02-169 | Wong, Yuken | 8/22/2011 | ML11238A028 | 9/28/2012 | ML12272A315 | Yes | Resolved - Closed |
| 522 | 6100 | 03.09.02-170 | Wong, Yuken | 10/26/2011 | ML11300A305 | 10/10/2012 | ML12286A069 | Yes | Resolved - Closed |
| 590 | 7146 | 03.09.02-171 | Wong, Yuken | 7/29/2013 | ML13254A063 | | | Yes | Issued/Waiting for Response |
| 590 | 7146 | 03.09.02-172 | Wong, Yuken | 7/29/2013 | ML13254A063 | | | Yes | Issued/Waiting for Response |
| 407 | 4654 | 03.09.02-69 | Wong, Yuken | 5/20/2010 | ML101580109 | 1/25/2012 | ML120530140 | Yes | Resolved - Closed |
| 407 | 4654 | 03.09.02-71 | Wong, Yuken | 5/20/2010 | ML101580109 | 1/25/2012 | ML120530140 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-87 | Wong, Yuken | 6/15/2010 | ML102150428 | 9/27/2011 | ML11270A388 | Yes | Resolved - Closed |
| 422 | 4792 | 03.09.02-99 | Wong, Yuken | 6/15/2010 | ML102150428 | 1/13/2012 | ML12016A013 | Yes | Resolved - Closed |
| 404 | 4684 | 03.09.03-25 | Le, Tuan | 5/11/2010 | ML101520140 | 8/11/2010 | ML102240044 | Yes | Resolved - Closed |
| 503 | 5444 | 03.09.03-26 | Le, Tuan | 7/29/2011 | ML12251A368 | 4/2/2012 | ML12093A076 | Yes | Resolved - Closed |
| 594 | 7193 | 03.09.03-27 | Le, Tuan | 7/29/2013 | ML13210A011 | | | Yes | Issued/Waiting for Response |
| 510 | 6016 | 03.09.05-28 | Spicher, Terri | 8/31/2011 | ML11285A034 | 3/20/2012 | ML12115A285 | Yes | Resolved - Closed |
| 510 | 6016 | 03.09.05-29 | Spicher, Terri | 8/31/2011 | ML11285A034 | 1/23/2012 | ML12024A541 | Yes | Unresolved - Closed |
| 510 | 6016 | 03.09.05-30 | Spicher, Terri | 8/31/2011 | ML11285A034 | 1/23/2012 | ML12024A541 | Yes | Unresolved - Closed |
| 522 | 6107 | 03.09.05-31 | Spicher, Terri | 10/26/2011 | ML11300A305 | 11/30/2011 | ML11334A169 | Yes | Resolved - Closed |
| 381 | 4529 | 03.09.06-15 | Hammer, Charles | 3/18/2010 | ML101110011 | 8/13/2010 | ML102250324 | Yes | Confirmatory Action |
| 381 | 4529 | 03.09.06-16 | Hammer, Charles | 3/18/2010 | ML101110011 | 8/13/2010 | ML102250324 | Yes | Resolved - Closed |
| 381 | 4529 | 03.09.06-17 | Hammer, Charles | 3/18/2010 | ML101110011 | 8/13/2010 | ML102250324 | Yes | Resolved - Closed |
| 477 | 5442 | 03.09.06-18 | Scarbrough, Thomas | 3/4/2011 | | 7/11/2011 | ML11192A207 | Yes | Resolved - Closed |
| 497 | 5837 | 03.09.06-19 | Scarbrough, Thomas | 7/1/2011 | ML11193A221 | 4/24/2012 | ML12115A354 | Yes | Resolved - Closed |
| 497 | 5837 | 03.09.06-19 | Scarbrough, Thomas | 7/1/2011 | ML11193A221 | 10/15/2012 | ML12293A315 | Yes | Resolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 585 | 7086 | 03.09.06-20 | Scarbrough, Thomas | 5/6/2013 | ML13126A339 | 5/15/2013 | ML13136A141 | Yes | Resolved - Closed |
| 612 | 7238 | 03.09.06-21 | Scarbrough, Thomas | 11/6/2013 | ML13310A734 | | | Yes | Issued/Waiting for Response |
| 612 | 7238 | 03.09.06-22 | Scarbrough, Thomas | 11/6/2013 | ML13310A734 | | | Yes | Issued/Waiting for Response |
| 612 | 7238 | 03.09.06-23 | Scarbrough, Thomas | 11/6/2013 | ML13310A734 | | | Yes | Issued/Waiting for Response |
| 249 | 2968 | 03.11-14 | Kang, Peter | 6/18/2009 | ML091910633 | 8/12/2009 | ML092240720 | Yes | Resolved - Closed |
| 377 | 4462 | 03.12-23 | Hsu, Kaihwa | 3/11/2010 | ML101470949 | 4/9/2010 | ML101020003 | Yes | Resolved - Closed |
| **Chapter 04 Total - 26 Question(s) / 26 Response(s)** | | | | | | | | | |
| | 7088 | | Patel, Amrit | | | | | Yes | Reviewed TBC |
| 318 | 3842 | 04.02-16 | Forsaty, Fred | 10/22/2009 | ML100040592 | 4/5/2010 | ML100960006 | Yes | Resolved - Closed |
| 339 | 4063 | 04.02-17 | Forsaty, Fred | 12/6/2009 | ML100081158 | 6/16/2010 | ML101690457 | Yes | In Evaluation |
| 571 | 7001 | 04.02-18 | Patel, Amrit | 2/8/2013 | ML13039A061 | 5/16/2013 | ML13137A079 | Yes | In Evaluation |
| 600 | 7197 | 04.02-19 | Schmidt, Jeffrey | 11/6/2013 | ML13310C180 | | | Yes | Issued/Waiting for Response |
| 344 | 4062 | 04.03-27 | Forsaty, Fred | 12/9/2009 | ML100541878 | 6/8/2010 | ML101600032 | Yes | Resolved - Closed |
| 344 | 4062 | 04.03-28 | Forsaty, Fred | 12/9/2009 | ML100541878 | 6/18/2010 | ML101600032 | Yes | Resolved - Closed |
| 205 | 2374 | 04.04-39 | Budzynski, John | 3/20/2009 | ML090980453 | 5/8/2009 | ML091330360 | Yes | Resolved - Closed |
| 205 | 2374 | 04.04-43 | Budzynski, John | 3/20/2009 | ML090980453 | 5/8/2009 | ML091330360 | Yes | Resolved - Closed |
| 308 | 3791 | 04.04-59 | Budzynski, John | 10/9/2009 | ML092940796 | 3/23/2010 | ML100850200 | Yes | Resolved - Closed |
| 308 | 3791 | 04.04-60 | Budzynski, John | 10/9/2009 | ML092940796 | 3/23/2010 | ML100850200 | Yes | Resolved - Closed |
| 325 | 3852 | 04.04-61 | Budzynski, John | 10/30/2009 | ML100040593 | 4/5/2010 | ML100960007 | Yes | Unresolved - Closed |
| 441 | 4970 | 04.04-62 | Budzynski, John | 9/1/2010 | ML102990326 | 5/20/2011 | ML11141A018 | Yes | Resolved - Closed |
| 441 | 4970 | 04.04-63 | Budzynski, John | 9/1/2010 | ML102990326 | 5/20/2011 | ML11141A018 | Yes | Resolved - Closed |
| 441 | 4970 | 04.04-64 | Budzynski, John | 9/1/2010 | ML102990326 | 5/20/2011 | ML11141A018 | Yes | Resolved - Closed |
| 441 | 4970 | 04.04-65 | Budzynski, John | 9/1/2010 | ML102990326 | 5/20/2011 | ML11141A018 | Yes | Resolved - Closed |
| 441 | 4970 | 04.04-66 | Budzynski, John | 9/1/2010 | ML102990326 | 5/20/2011 | ML11141A018 | Yes | Resolved - Closed |
| 544 | 6411 | 04.04-67 | Hayes(NRO), Michelle | 4/5/2012 | ML12103A495 | 6/7/2013 | ML13158A005 | Yes | Confirmatory Action |
| 544 | 6411 | 04.04-68 | Hayes(NRO), Michelle | 4/5/2012 | ML12103A495 | 6/7/2013 | ML13158A005 | Yes | Resolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 343 | 4119 | 04.05.01-6 | Davis, Robert | 12/7/2009 | ML093500085 | 6/8/2010 | ML101600031 | Yes | Resolved - Closed |
| 343 | 4119 | 04.05.01-7 | Davis, Robert | 12/7/2009 | ML093500085 | 6/8/2010 | ML101600031 | Yes | Resolved - Closed |
| 339 | 4056 | 04.05.02-10 | Honcharik, John | 12/6/2009 | ML100081158 | 6/16/2010 | ML101690457 | Yes | Resolved - Closed |
| 339 | 4056 | 04.05.02-11 | Honcharik, John | 12/6/2009 | ML100081158 | 6/16/2010 | ML101690457 | Yes | Resolved - Closed |
| 339 | 4056 | 04.05.02-9 | Honcharik, John | 12/6/2009 | ML100081158 | 6/16/2010 | ML101690457 | Yes | Resolved - Closed |
| 366 | 4366 | 04.06-13 | Budzynski, John | 2/3/2010 | ML100560002 | 6/29/2010 | ML101810141 | Yes | Resolved - Closed |
| 367 | 4369 | 04.06-14 | Budzynski, John | 2/4/2010 | ML100700711 | 6/7/2011 | ML11159A264 | Yes | In Evaluation |
| **Chapter 05 Total - 33 Question(s) / 34 Response(s)** | | | | | | | | | |
| 365 | 4317 | 05.02.01.01-5 | Wu, Cheng-Ih | 2/3/2010 | ML101170319 | 5/24/2010 | ML101440244 | Yes | Unresolved - Closed |
| 365 | 4317 | 05.02.01.01-5 | Wu, Cheng-Ih | 2/3/2010 | ML101170319 | 2/5/2014 | ML14036A368 | Yes | Unresolved - Closed |
| 444 | 4995 | 05.02.01.01-6 | Wu, Cheng-Ih | 9/14/2010 | ML102630005 | 5/16/2011 | ML11137A001 | Yes | Unresolved - Closed |
| 560 | 6808 | 05.02.01.01-7 | Wu, Cheng-Ih | 10/2/2012 | ML12284A029 | 11/1/2012 | ML12333A379 | Yes | Resolved - Closed |
| 332 | 4047 | 05.02.02-11 | Budzynski, John | 11/18/2009 | ML093520100 | 3/1/2010 | ML100600988 | Yes | Resolved - Closed |
| 332 | 4047 | 05.02.02-12 | Budzynski, John | 11/18/2009 | ML093520100 | 3/1/2010 | ML100600988 | Yes | Resolved - Closed |
| 88 | 1239 | 05.02.03-1 | Davis, Robert | 9/26/2008 | ML083010114 | 11/10/2008 | ML083151416 | Yes | Unresolved - Closed |
| 278 | 3466 | 05.02.03-20 | Davis, Robert | 8/17/2009 | ML092570749 | 5/20/2011 | ML11141A025 | Yes | Resolved - Closed |
| 278 | 3466 | 05.02.03-21 | Davis, Robert | 8/17/2009 | ML092570749 | 8/27/2010 | ML102390581 | Yes | Resolved - Closed |
| 278 | 3466 | 05.02.03-22 | Davis, Robert | 8/17/2009 | ML092570749 | 8/27/2010 | ML102390581 | Yes | Resolved - Closed |
| 278 | 3466 | 05.02.03-23 | Davis, Robert | 8/17/2009 | ML092570749 | 8/27/2010 | ML102390581 | Yes | Resolved - Closed |
| 365 | 4318 | 05.02.05-10 | Li, Chang | 2/3/2010 | ML101170319 | 4/27/2010 | ML101180189 | Yes | Resolved - Closed |
| 365 | 4318 | 05.02.05-11 | Li, Chang | 2/3/2010 | ML101170319 | 4/27/2010 | ML101180189 | Yes | Unresolved - Closed |
| 431 | 4977 | 05.02.05-12 | Li, Chang | 8/5/2010 | ML102510086 | 1/31/2011 | ML110320006 | Yes | Resolved - Closed |
| 478 | 5434 | 05.02.05-13 | Li, Chang | 3/4/2011 | ML110660677 | 8/26/2011 | ML11238A086 | Yes | Resolved - Closed |
| 244 | 2958 | 05.02.05-5 | Li, Chang | 6/5/2009 | ML091660751 | 7/14/2009 | ML091950755 | Yes | Resolved - Closed |
| 244 | 2958 | 05.02.05-6 | Li, Chang | 6/5/2009 | ML091660751 | 7/14/2009 | ML091950755 | Yes | Unresolved - Closed |
| 244 | 2958 | 05.02.05-7 | Li, Chang | 6/5/2009 | ML091660751 | 7/14/2009 | ML091950755 | Yes | Unresolved - Closed |

# eRAI Question Status Report
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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 244 | 2958 | 05.02.05-8 | Li, Chang | 6/5/2009 | ML091660751 | 7/14/2009 | ML091950755 | Yes | Unresolved - Closed |
| 365 | 4318 | 05.02.05-9 | Li, Chang | 2/3/2010 | ML101170319 | 4/27/2010 | ML101180189 | Yes | Resolved - Closed |
| 357 | 4205 | 05.03.01-13 | Jenkins, Joel | 1/10/2010 | ML100120429 | 7/27/2010 | ML102080393 | Yes | Resolved - Closed |
| 365 | 4319 | 05.03.01-14 | Jenkins, Joel | 2/3/2010 | ML101170319 | 4/27/2010 | ML101180189 | Yes | Resolved - Closed |
| 365 | 4319 | 05.03.01-15 | Jenkins, Joel | 2/3/2010 | ML101170319 | 4/27/2010 | ML101180189 | Yes | Resolved - Closed |
| 278 | 3506 | 05.03.02-10 | Downey, Steven | 8/17/2009 | ML092570749 | 8/27/2010 | ML102390581 | Yes | Resolved - Closed |
| 531 | 6195 | 05.03.02-11 | Jenkins, Joel | 11/25/2011 | ML11354A354 | 4/13/2012 | ML12104A220 | Yes | Resolved - Closed |
| 64 | 996 | 05.03.02-5 | Allison Black | 8/27/2008 | ML082790055 | 4/30/2009 | ML091200758 | Yes | Resolved - Closed |
| 278 | 3506 | 05.03.02-7 | Downey, Steven | 8/17/2009 | ML092570749 | 8/27/2010 | ML102390581 | Yes | Resolved - Closed |
| 278 | 3506 | 05.03.02-8 | Downey, Steven | 8/17/2009 | ML092570749 | 8/27/2010 | ML102390581 | Yes | Resolved - Closed |
| 278 | 3506 | 05.03.02-9 | Downey, Steven | 8/17/2009 | ML092570749 | 8/27/2010 | ML102390581 | Yes | Resolved - Closed |
| 341 | 4042 | 05.04.01.01-2 | Honcharik, John | 12/6/2009 | ML093490198 | 2/27/2010 | ML100600275 | Yes | Resolved - Closed |
| 341 | 4042 | 05.04.01.01-3 | Honcharik, John | 12/6/2009 | ML093490198 | 2/27/2010 | ML100600275 | Yes | Unresolved - Closed |
| 341 | 4042 | 05.04.01.01-4 | Honcharik, John | 12/6/2009 | ML093490198 | 2/27/2010 | ML100600275 | Yes | Resolved - Closed |
| 364 | 4327 | 05.04.02.02-16 | Makar, Gregory | 2/2/2010 | ML100330855 | 3/1/2010 | ML100610003 | Yes | Resolved - Closed |
| 342 | 3933 | 05.04.12-5 | Budzynski, John | 12/7/2009 | ML100190105 | 3/1/2010 | ML100601324 | Yes | Resolved - Closed |
| **Chapter 06 Total - 83 Question(s) / 98 Response(s)** | | | | | | | | | |
| 81 | 1154 | 06.01.02-1 | Poehler, Jeffrey | 9/15/2008 | ML082790104 | 11/3/2008 | ML083110385 | Yes | Unresolved - Closed |
| 480 | 5625 | 06.01.02-10 | Sastre, Eduardo | 3/11/2011 | ML110761114 | 9/1/2011 | ML11244A053 | Yes | Resolved - Closed |
| 480 | 5625 | 06.01.02-11 | Sastre, Eduardo | 3/11/2011 | ML110761114 | 9/1/2011 | ML11244A053 | Yes | Resolved - Closed |
| 203 | 2253 | 06.01.02-7 | Poehler, Jeffrey | 3/11/2009 | ML090840417 | 4/23/2009 | ML091130561 | Yes | Unresolved - Closed |
| 475 | 5558 | 06.02.01.01.A-1 | Jensen, Walton | 2/22/2011 | ML110660671 | 9/22/2011 | ML11265A342 | Yes | Resolved - Closed |
| 540 | 6300 | 06.02.01.01.A-3 | Peng, Shie-Jeng | 3/2/2012 | ML12250A857 | 7/3/2012 | ML12186A000 | Yes | Resolved - Closed |
| 451 | 5136 | 06.02.01.04-8 | Jensen, Walton | 10/8/2010 | ML102930005 | 5/25/2011 | ML11146A165 | Yes | Resolved - Closed |
| 540 | 6308 | 06.02.01.05-2 | Peng, Shie-Jeng | 3/2/2012 | ML12250A857 | 6/13/2012 | ML12167A001 | Yes | Resolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 437 | 4953 | 06.02.01-100 | Jensen, Walton | 8/18/2010 | ML102930007 | 8/10/2011 | ML11223A015 | Yes | Resolved - Closed |
| 479 | 5568 | 06.02.01-102 | Jensen, Walton | 3/4/2011 | ML110660676 | 8/31/2011 | ML11243A167 | Yes | Resolved - Closed |
| 515 | 6061 | 06.02.01-103 | Peng, Shie-Jeng | 9/23/2011 | ML11272A251 | 6/6/2012 | ML12164A170 | Yes | Resolved - Closed |
| 537 | 6248 | 06.02.01-104 | Peng, Shie-Jeng | 12/23/2011 | ML12102A050 | 7/27/2012 | ML12179A293 | Yes | Resolved - Closed |
| 598 | 7210 | 06.02.01-106 | Peng, Shie-Jeng | 8/14/2013 | | | | Yes | Issued/Waiting for Response |
| 221 | 2792 | 06.02.01-38 | Jensen, Walton | 5/7/2009 | ML091390886 | 8/27/2009 | ML092390663 | Yes | Resolved - Closed |
| 368 | 4344 | 06.02.01-70 | Jensen, Walton | 2/9/2010 | ML100780536 | 9/26/2011 | ML11269A237 | Yes | Resolved - Closed |
| 368 | 4344 | 06.02.01-71 | Jensen, Walton | 2/9/2010 | ML100780536 | 8/25/2011 | ML11243A170 | Yes | Resolved - Closed |
| 368 | 4344 | 06.02.01-73 | Jensen, Walton | 2/9/2010 | ML100780536 | 8/25/2011 | ML11243A170 | Yes | Resolved - Closed |
| 368 | 4344 | 06.02.01-80 | Jensen, Walton | 2/9/2010 | ML100780536 | 8/25/2011 | ML11243A170 | Yes | Resolved - Closed |
| 378 | 4409 | 06.02.01-88 | Jensen, Walton | 3/17/2010 | ML101130142 | 8/12/2010 | ML102250101 | Yes | Resolved - Closed |
| 378 | 4409 | 06.02.01-93 | Jensen, Walton | 3/17/2010 | ML101130142 | 10/26/2011 | ML11299A190 | Yes | Resolved - Closed |
| 437 | 4953 | 06.02.01-96 | Jensen, Walton | 8/18/2010 | ML102930007 | 6/15/2011 | ML11167A086 | Yes | Resolved - Closed |
| 437 | 4953 | 06.02.01-97 | Jensen, Walton | 8/18/2010 | ML102930007 | 6/15/2011 | ML11167A086 | Yes | Resolved - Closed |
| 437 | 4953 | 06.02.01-98 | Jensen, Walton | 8/18/2010 | ML102930007 | 6/15/2011 | ML11167A086 | Yes | Resolved - Closed |
| 437 | 4953 | 06.02.01-99 | Jensen, Walton | 8/18/2010 | ML102930007 | 10/3/2011 | ML11277A004 | Yes | Resolved - Closed |
| 511 | 6020 | 06.02.02-126 | Scarbrough, Thomas | 8/31/2011 | ML11264A174 | 3/29/2013 | ML13088A307 | Yes | Resolved - Closed |
| 524 | 6181 | 06.02.02-127 | Ashley, Clinton | 11/4/2011 | ML11315A002 | | | Yes | Issued/Waiting for Response |
| 546 | 6407 | 06.02.02-130 | Makar, Gregory | 4/18/2012 | ML12116A163 | 10/4/2012 | ML12278A194 | Yes | Resolved - Closed |
| 546 | 6407 | 06.02.02-132 | Makar, Gregory | 4/18/2012 | ML12116A163 | 10/4/2012 | ML12278A194 | Yes | Confirmatory Action |
| 546 | 6407 | 06.02.02-133 | Makar, Gregory | 4/18/2012 | ML12116A163 | 10/4/2012 | ML12278A194 | Yes | Confirmatory Action |
| 569 | 6958 | 06.02.02-136 | Strnisha, James | 12/7/2012 | | 4/11/2013 | ML13121A408 | Yes | Confirmatory Action |
| 569 | 6958 | 06.02.02-137 | Strnisha, James | 12/7/2012 | | 4/11/2013 | ML13121A408 | Yes | Confirmatory Action |
| 569 | 6958 | 06.02.02-138 | Strnisha, James | 12/7/2012 | | 4/11/2013 | ML13121A408 | Yes | Resolved - Closed |
| 569 | 6958 | 06.02.02-139 | Strnisha, James | 12/7/2012 | | 4/11/2013 | ML13121A408 | Yes | Resolved - Closed |
| 389 | 4615 | 06.02.02-47 | Peng, Shie-Jeng | 4/12/2010 | ML101530010 | 6/1/2011 | ML11154A184 | Yes | Resolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 389 | 4615 | 06.02.02-51 | Peng, Shie-Jeng | 4/12/2010 | ML101530010 | 6/1/2011 | ML11154A184 | Yes | Resolved - Closed |
| 434 | 4897 | 06.02.02-72 | Ashley, Clinton | 8/6/2010 | ML102880430 | 2/10/2012 | ML12041A430 | Yes | Resolved - Closed |
| 434 | 4897 | 06.02.02-72 | Ashley, Clinton | 8/6/2010 | ML102880430 | 5/13/2013 | ML13136A060 | Yes | Resolved - Closed |
| 475 | 5557 | 06.02.02-86 | Ashley, Clinton | 2/22/2011 | ML110660671 | 12/15/2011 | ML11350A034 | Yes | Issued/Waiting for Response |
| 475 | 5557 | 06.02.02-87 | Ashley, Clinton | 2/22/2011 | ML110660671 | 12/15/2011 | ML11350A034 | Yes | Issued/Waiting for Response |
| 475 | 5557 | 06.02.02-87 | Ashley, Clinton | 2/22/2011 | ML110660671 | 5/13/2013 | ML13136A064 | Yes | Issued/Waiting for Response |
| 378 | 4490 | 06.02.03-6 | Jackson, Christopher | 3/17/2010 | ML101130142 | 5/25/2011 | ML11146A163 | Yes | Unresolved - Closed |
| 462 | 5258 | 06.02.03-7 | ODriscoll, James | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Resolved - Closed |
| 462 | 5258 | 06.02.03-8 | Chien, Nan | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Confirmatory Action |
| 462 | 5258 | 06.02.03-8 | Chien, Nan | 12/8/2010 | ML110260460 | 2/22/2013 | ML13065A143 | Yes | Confirmatory Action |
| 462 | 5258 | 06.02.03-8 | Chien, Nan | 12/8/2010 | ML110260460 | 5/17/2013 | ML13139A008 | Yes | Confirmatory Action |
| 410 | 4719 | 06.02.04-10 | Grady, Anne-Marie | 5/25/2010 | ML102600224 | 11/3/2010 | ML103090114 | Yes | Unresolved - Closed |
| 479 | 5610 | 06.02.04-11 | Grady, Anne-Marie | 3/4/2011 | ML110660676 | 10/13/2011 | ML11286A426 | Yes | Unresolved - Closed |
| 479 | 5612 | 06.02.04-12 | Grady, Anne-Marie | 3/4/2011 | ML110660676 | 8/31/2011 | ML11243A167 | Yes | Resolved - Closed |
| 568 | 6713 | 06.02.04-13 | Grady, Anne-Marie | 12/11/2012 | ML12346A470 | 2/28/2013 | ML13066A009 | Yes | Resolved - Closed |
| 372 | 4388 | 06.02.04-9 | Grady, Anne-Marie | 2/25/2010 | ML100680438 | 5/26/2010 | ML101470362 | Yes | Resolved - Closed |
| 323 | 3903 | 06.02.05-10 | Grady, Anne-Marie | 10/30/2009 | ML093230856 | 3/3/2010 | ML100621411 | Yes | Resolved - Closed |
| 471 | 5389 | 06.02.05-20 | Grady, Anne-Marie | 1/25/2011 | ML110460506 | 2/15/2011 | ML12146A156 | Yes | Unresolved - Closed |
| 471 | 5389 | 06.02.05-20 | Grady, Anne-Marie | 1/25/2011 | ML110460506 | 7/12/2013 | ML13196A060 | Yes | Unresolved - Closed |
| 471 | 5389 | 06.02.05-21 | Grady, Anne-Marie | 1/25/2011 | ML110460506 | 7/12/2013 | ML13196A060 | Yes | Unresolved - Closed |
| 471 | 5389 | 06.02.05-21 | Grady, Anne-Marie | 1/25/2011 | ML110460506 | 2/15/2011 | ML12146A156 | Yes | Unresolved - Closed |
| 471 | 5389 | 06.02.05-22 | Grady, Anne-Marie | 1/25/2011 | ML110460506 | 8/17/2011 | ML11230B306 | Yes | Unresolved - Closed |
| 471 | 5389 | 06.02.05-23 | Grady, Anne-Marie | 1/25/2011 | ML110460506 | 2/15/2011 | ML12146A156 | Yes | Unresolved - Closed |
| 473 | 5531 | 06.02.05-24 | Grady, Anne-Marie | 2/15/2011 | ML110660666 | 6/26/2013 | ML13177A456 | Yes | Unresolved - Closed |
| 474 | 5550 | 06.02.05-25 | Grady, Anne-Marie | 2/17/2011 | ML110670512 | 7/16/2012 | ML12200A276 | Yes | Unresolved - Closed |
| 515 | 6041 | 06.02.05-26 | Grady, Anne-Marie | 9/23/2011 | ML11272A251 | 4/2/2012 | ML12093A393 | Yes | Resolved - Closed |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 540 | 6329 | 06.02.05-27 | Grady, Anne-Marie | 3/2/2012 | ML12250A857 | 7/16/2012 | ML12200A277 | Yes | Resolved - Closed |
| 540 | 6329 | 06.02.05-28 | Grady, Anne-Marie | 3/2/2012 | ML12250A857 | 7/16/2012 | ML12200A277 | Yes | Resolved - Closed |
| 540 | 6329 | 06.02.05-29 | Grady, Anne-Marie | 3/2/2012 | ML12250A857 | 7/16/2012 | ML12200A277 | Yes | Resolved - Closed |
| 540 | 6329 | 06.02.05-30 | Grady, Anne-Marie | 3/2/2012 | ML12250A857 | 7/16/2012 | ML12200A277 | Yes | Unresolved - Closed |
| 553 | 6573 | 06.02.05-31 | Grady, Anne-Marie | 7/25/2012 | ML12207A613 | 1/29/2014 | ML14029A624 | Yes | Resolved - Closed |
| 553 | 6573 | 06.02.05-31 | Grady, Anne-Marie | 7/25/2012 | ML12207A613 | 6/28/2013 | ML13192A094 | Yes | Resolved - Closed |
| 566 | 6955 | 06.02.05-32 | Grady, Anne-Marie | 2/8/2013 | ML13039A063 | 11/19/2013 | ML13345B333 | Yes | Resolved - Closed |
| 566 | 6955 | 06.02.05-32 | Grady, Anne-Marie | 2/8/2013 | ML13039A063 | 4/30/2013 | ML13120A202 | Yes | Resolved - Closed |
| 574 | 7018 | 06.02.05-33 | Grady, Anne-Marie | 3/12/2013 | ML13071A485 | 6/14/2013 | ML13171A019 | Yes | Resolved - Closed |
| 574 | 7018 | 06.02.05-34 | Grady, Anne-Marie | 3/12/2013 | ML13071A485 | 6/14/2013 | ML13171A019 | Yes | Resolved - Closed |
| 597 | 7207 | 06.02.05-35 | Grady, Anne-Marie | 8/14/2013 | | | | Yes | Issued/Waiting for Response |
| 310 | 3709 | 06.03-14 | Budzynski, John | 10/9/2009 | ML092940798 | 11/20/2009 | ML093240544 | Yes | In Evaluation |
| 416 | 4749 | 06.03-15 | Ashley, Clinton | 6/8/2010 | ML102380580 | 6/29/2011 | ML11180A055 | Yes | Unresolved - Closed |
| 429 | 4914 | 06.03-16 | Budzynski, John | 7/21/2010 | ML102880724 | 6/29/2011 | ML11180A179 | Yes | Resolved - Closed |
| 480 | 5573 | 06.03-17 | Budzynski, John | 3/11/2011 | ML110761114 | 11/9/2011 | ML11314A227 | Yes | Resolved - Closed |
| 553 | 6463 | 06.03-18 | Budzynski, John | 6/26/2012 | ML12207A613 | 2/1/2013 | ML13065A117 | Yes | Issued/Waiting for Response |
| 553 | 6463 | 06.03-18 | Budzynski, John | 6/26/2012 | ML12207A613 | 2/14/2013 | ML13065A135 | Yes | Issued/Waiting for Response |
| 553 | 6463 | 06.03-18 | Budzynski, John | 6/26/2012 | ML12207A613 | 8/9/2013 | ML13254A071 | Yes | Issued/Waiting for Response |
| 553 | 6463 | 06.03-18 | Budzynski, John | 6/26/2012 | ML12207A613 | 5/13/2013 | ML13136A069 | Yes | Issued/Waiting for Response |
| 626 | 7281 | 06.03-19 | Budzynski, John | 3/5/2014 | ML14064A294 | 5/7/2014 | ML14127A299 | Yes | In Evaluation |
| 32 | 576 | 06.03-3 | Budzynski, John | 7/11/2008 | ML082240484 | 8/28/2008 | ML082470013 | Yes | Resolved - Closed |
| 32 | 578 | 06.03-4 | Budzynski, John | 7/11/2008 | ML082240484 | 8/28/2008 | ML082470013 | Yes | Resolved - Closed |
| 511 | 6012 | 06.04-10 | Chien, Nan | 8/31/2011 | ML11264A174 | 5/17/2013 | ML13139A012 | Yes | Confirmatory Action |
| 511 | 6012 | 06.04-10 | Chien, Nan | 8/31/2011 | ML11264A174 | 5/10/2013 | ML14066A240 | Yes | Confirmatory Action |
| 511 | 6012 | 06.04-11 | ODriscoll, James | 8/31/2011 | ML11264A174 | 3/29/2013 | ML13088A307 | Yes | Resolved - Closed |
| 462 | 5259 | 06.04-5 | ODriscoll, James | 12/8/2010 | ML110260460 | 6/29/2011 | ML11181A260 | Yes | Resolved - Closed |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 462 | 5259 | 06.04-6 | ODriscoll, James | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Unresolved - Closed |
| 462 | 5259 | 06.04-7 | ODriscoll, James | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Unresolved - Closed |
| 462 | 5259 | 06.04-7 | ODriscoll, James | 12/8/2010 | ML110260460 | 8/2/2012 | ML12216A208 | Yes | Unresolved - Closed |
| 462 | 5259 | 06.04-8 | ODriscoll, James | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Unresolved - Closed |
| 511 | 6012 | 06.04-9 | Chien, Nan | 8/31/2011 | ML11264A174 | 5/17/2013 | ML13139A012 | Yes | Confirmatory Action |
| 462 | 5260 | 06.05.01-2 | ODriscoll, James | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Resolved - Closed |
| 462 | 5260 | 06.05.01-3 | ODriscoll, James | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Resolved - Closed |
| 462 | 5260 | 06.05.01-4 | ODriscoll, James | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Resolved - Closed |
| 462 | 5260 | 06.05.01-5 | ODriscoll, James | 12/8/2010 | ML110260460 | 7/22/2011 | ML11203A409 | Yes | Resolved - Closed |
| 233 | 2873 | 06.05.03-1 | Chien, Nan | 5/19/2009 | ML091630743 | 9/1/2009 | ML092440834 | Yes | Confirmatory Action |
| 233 | 2873 | 06.05.03-1 | Chien, Nan | 5/19/2009 | ML091630743 | 4/25/2013 | ML13116A071 | Yes | Confirmatory Action |
| 233 | 2873 | 06.05.03-1 | Chien, Nan | 5/19/2009 | ML091630743 | 6/25/2013 | ML13176A458 | Yes | Confirmatory Action |
| **Chapter 07 Total - 69 Question(s) / 76 Response(s)** | | | | | | | | | |
| 505 | 5902 | 07.01-33 | Zhang, Deanna | 8/12/2011 | ML11242A135 | | | Yes | Issued/Waiting for Response |
| 505 | 5902 | 07.01-34 | Morton, Wendell | 8/12/2011 | ML11242A135 | 5/9/2012 | ML12135A646 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-35 | Morton, Wendell | 8/12/2011 | ML11242A135 | 4/19/2013 | ML13113A238 | Yes | Unresolved - Closed |
| 505 | 5902 | 07.01-36 | Morton, Wendell | 8/12/2011 | ML11242A135 | 4/27/2012 | ML12118A537 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-36 | Morton, Wendell | 8/12/2011 | ML11242A135 | 12/19/2012 | ML13012A006 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-37 | Morton, Wendell | 8/12/2011 | ML11242A135 | 4/17/2012 | ML12108A145 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-38 | Morton, Wendell | 8/12/2011 | ML11242A135 | 4/11/2012 | ML12102A157 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-39 | Morton, Wendell | 8/12/2011 | ML11242A135 | 5/22/2012 | ML12146A158 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-39 | Morton, Wendell | 8/12/2011 | ML11242A135 | 12/19/2012 | ML13012A006 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-40 | Morton, Wendell | 8/12/2011 | ML11242A135 | 5/22/2012 | ML12146A158 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-41 | Morton, Wendell | 8/12/2011 | ML11242A135 | 3/16/2012 | ML12077A001 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-42 | Morton, Wendell | 8/12/2011 | ML11242A135 | 1/19/2012 | ML12019A397 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-43 | Morton, Wendell | 8/12/2011 | ML11242A135 | 11/22/2011 | ML11326A257 | Yes | Resolved - Closed |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 505 | 5902 | 07.01-44 | Morton, Wendell | 8/12/2011 | ML11242A135 | 5/9/2012 | ML12135A646 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-44 | Morton, Wendell | 8/12/2011 | ML11242A135 | 12/19/2012 | ML12301A006 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-45 | Morton, Wendell | 8/12/2011 | ML11242A135 | 4/19/2012 | ML12110A310 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-46 | Morton, Wendell | 8/12/2011 | ML11242A135 | 4/27/2012 | ML12118A537 | Yes | Unresolved - Closed |
| 505 | 5902 | 07.01-47 | Morton, Wendell | 8/12/2011 | ML11242A135 | 5/22/2012 | ML12146A158 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-48 | Morton, Wendell | 8/12/2011 | ML11242A135 | 5/9/2012 | ML12135A646 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-48 | Morton, Wendell | 8/12/2011 | ML11242A135 | 7/20/2012 | ML12202B124 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-48 | Morton, Wendell | 8/12/2011 | ML11242A135 | 7/6/2012 | ML12194A050 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-49 | Morton, Wendell | 8/12/2011 | ML11242A135 | 5/29/2012 | ML12150A406 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-50 | Truong, Tung | 8/12/2011 | ML11242A135 | 4/18/2012 | ML12115A353 | Yes | Resolved - Closed |
| 505 | 5902 | 07.01-51 | Morton, Wendell | 8/12/2011 | ML11242A135 | 5/22/2012 | ML12146A158 | Yes | Resolved - Closed |
| 542 | 6336 | 07.01-52 | Morton, Wendell | 3/2/2012 | | 4/12/2013 | ML13102A179 | Yes | Unresolved - Closed |
| 555 | 6611 | 07.01-53 | Morton, Wendell | 8/15/2012 | | 5/31/2013 | ML13154A504 | Yes | Issued/Waiting for Response |
| 555 | 6611 | 07.01-54 | Morton, Wendell | 8/15/2012 | | 2/21/2013 | ML13065A140 | Yes | Resolved - Closed |
| 555 | 6611 | 07.01-55 | Morton, Wendell | 8/15/2012 | | 2/21/2013 | ML13065A140 | Yes | Unresolved - Closed |
| 608 | 7222 | 07.01-56 | Morton, Wendell | 1/14/2014 | | | | Yes | Issued/Waiting for Response |
| 608 | 7222 | 07.01-57 | Morton, Wendell | 1/14/2014 | | | | Yes | Issued/Waiting for Response |
| 608 | 7222 | 07.01-58 | Zhang, Deanna | 1/14/2014 | | | | Yes | Issued/Waiting for Response |
| 608 | 7222 | 07.01-59 | Zhang, Deanna | 1/14/2014 | | | | Yes | Issued/Waiting for Response |
| 608 | 7222 | 07.01-60 | Zhang, Deanna | 1/14/2014 | | | | Yes | Issued/Waiting for Response |
| 608 | 7222 | 07.01-61 | Morton, Wendell | 1/14/2014 | | | | Yes | Issued/Waiting for Response |
| 608 | 7222 | 07.01-62 | Morton, Wendell | 1/14/2014 | | | | Yes | Issued/Waiting for Response |
| 608 | 7222 | 07.01-63 | Morton, Wendell | 1/14/2014 | | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-64 | Mott, Kenneth | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-65 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-66 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 609 | 7223 | 07.01-67 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-68 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-69 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-70 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-71 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-72 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-73 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-74 | Zhang, Deanna | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-75 | Zhang, Deanna | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-76 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-77 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-78 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-79 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-80 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-81 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-82 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 609 | 7223 | 07.01-83 | Morton, Wendell | 1/14/2014 | ML14014A229 | | | Yes | Issued/Waiting for Response |
| 611 | 7259 | 07.01-84 | Morton, Wendell | 4/14/2014 | ML14104B192 | | | Yes | Issued/Waiting for Response |
| 414 | 4398 | 07.03-30 | Morton, Wendell | 6/8/2010 | ML101660734 | 3/8/2013 | ML13085A168 | Yes | Resolved - Closed |
| 414 | 4398 | 07.03-30 | Morton, Wendell | 6/8/2010 | ML101660734 | 5/22/2012 | ML12144A205 | Yes | Resolved - Closed |
| 505 | 5735 | 07.03-37 | Morton, Wendell | 8/12/2011 | ML11242A135 | 12/15/2011 | ML11350A033 | Yes | Resolved - Closed |
| 505 | 5735 | 07.03-38 | Morton, Wendell | 8/12/2011 | ML11242A135 | 4/17/2012 | ML12108A145 | Yes | Resolved - Closed |
| 505 | 5869 | 07.04-15 | Spaulding, Deirdre | 8/12/2011 | ML11242A135 | 12/15/2011 | ML11350A033 | Yes | Resolved - Closed |
| 505 | 5754 | 07.05-10 | Spaulding, Deirdre | 8/12/2011 | ML11242A135 | 3/16/2012 | ML12077A001 | Yes | Unresolved - Closed |
| 505 | 5754 | 07.05-11 | Spaulding, Deirdre | 8/12/2011 | ML11242A135 | 12/15/2011 | ML11350A033 | Yes | Resolved - Closed |
| 505 | 5803 | 07.07-23 | Mott, Kenneth | 8/12/2011 | ML11242A135 | 11/22/2011 | ML11326A257 | Yes | Resolved - Closed |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 505 | 5950 | 07.08-43 | Mott, Kenneth | 8/12/2011 | ML11242A135 | 12/15/2011 | ML11350A033 | Yes | Resolved - Closed |
| 505 | 5950 | 07.08-44 | Mott, Kenneth | 8/12/2011 | ML11242A135 | 1/10/2012 | ML12013A085 | Yes | Resolved - Closed |
| 505 | 5950 | 07.08-45 | Mott, Kenneth | 8/12/2011 | ML11242A135 | 12/15/2011 | ML11350A033 | Yes | Resolved - Closed |
| 505 | 5950 | 07.08-46 | Mott, Kenneth | 8/12/2011 | ML11242A135 | 3/16/2012 | ML12077A001 | Yes | Resolved - Closed |
| 505 | 5950 | 07.08-47 | Mott, Kenneth | 8/12/2011 | ML11242A135 | 4/3/2012 | ML12094A369 | Yes | Resolved - Closed |
| 505 | 5950 | 07.08-48 | Mott, Kenneth | 8/12/2011 | ML11242A135 | 1/10/2012 | ML12013A085 | Yes | Resolved - Closed |
| 505 | 5950 | 07.08-49 | Mott, Kenneth | 8/12/2011 | ML11242A135 | 12/15/2011 | ML11350A033 | Yes | Resolved - Closed |
| 512 | 6048 | 07.08-50 | Mott, Kenneth | 9/13/2011 | ML11257A254 | 5/30/2012 | ML12152A002 | Yes | Resolved - Closed |
| 512 | 6048 | 07.08-50 | Mott, Kenneth | 9/13/2011 | ML11257A254 | 7/20/2012 | ML12202B132 | Yes | Resolved - Closed |
| 505 | 5744 | 07.09-71 | Zhang, Deanna | 8/12/2011 | ML11242A135 | 4/27/2012 | ML12118A537 | Yes | Resolved - Closed |
| 505 | 5744 | 07.09-72 | Zhang, Deanna | 8/12/2011 | ML11242A135 | 4/18/2012 | ML12115A353 | Yes | Resolved - Closed |
| **Chapter 08 Total - 5 Question(s) / 7 Response(s)** | | | | | | | | | |
| 9 | 182 | 08.01-3 | Kang, Peter | 6/12/2008 | ML081640044 | 7/11/2008 | ML081970251 | Yes | Resolved - Closed |
| 9 | 223 | 08.02-6 | Kang, Peter | 6/12/2008 | ML081640044 | 9/30/2008 | ML082790016 | Yes | Resolved - Closed |
| 564 | 6901 | 08.02-8 | Kang, Peter | 11/23/2012 | ML12331A358 | 7/16/2013 | ML13197A513 | Yes | In Evaluation |
| 564 | 6901 | 08.02-8 | Kang, Peter | 11/23/2012 | ML12331A358 | 10/25/2013 | ML13316C460 | Yes | In Evaluation |
| 564 | 6901 | 08.02-8 | Kang, Peter | 11/23/2012 | ML12331A358 | 8/2/2013 | ML13218A208 | Yes | In Evaluation |
| 11 | 224 | 08.03.01-7 | Kang, Peter | 6/16/2008 | ML081680649 | 9/25/2008 | ML082790010 | Yes | Resolved - Closed |
| 11 | 226 | 08.04-4 | Kang, Peter | 6/16/2008 | ML081680649 | 7/16/2008 | ML081980827 | Yes | Resolved - Closed |
| **Chapter 09 Total - 91 Question(s) / 93 Response(s)** | | | | | | | | | |
| 263 | 3237 | 09.01.01-24 | Poehler, Jeffrey | 7/17/2009 | ML092110819 | 12/9/2009 | ML093431316 | Yes | Resolved - Closed |
| 513 | 5971 | 09.01.01-53 | Patel, Amrit | 9/13/2011 | ML11273A171 | 12/13/2012 | ML13012A003 | Yes | Resolved - Closed |
| 513 | 5971 | 09.01.01-54 | Patel, Amrit | 9/13/2011 | ML11273A171 | | | Yes | Resolved - Closed |
| 513 | 5971 | 09.01.01-56 | Patel, Amrit | 9/13/2011 | ML11273A171 | 4/24/2012 | ML12115A357 | Yes | Resolved - Closed |
| 513 | 5971 | 09.01.01-57 | Patel, Amrit | 9/13/2011 | ML11273A171 | 8/17/2012 | ML12233A181 | Yes | Resolved - Closed |
| 513 | 5971 | 09.01.01-58 | Patel, Amrit | 9/13/2011 | ML11273A171 | 7/12/2013 | ML13196A059 | Yes | In Evaluation |

# eRAI Question Status Report
# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 513 | 5971 | 09.01.01-60 | Patel, Amrit | 9/13/2011 | ML11273A171 | 8/17/2012 | ML12233A181 | Yes | Resolved - Closed |
| 513 | 5971 | 09.01.01-61 | Patel, Amrit | 9/13/2011 | ML11273A171 | 6/27/2013 | ML13178A378 | Yes | In Evaluation |
| 513 | 5971 | 09.01.01-62 | Patel, Amrit | 9/13/2011 | ML11273A171 | 6/27/2013 | ML13178A378 | Yes | In Evaluation |
| 538 | 6295 | 09.01.01-63 | VanWert, Christopher | 1/19/2012 | ML12026A814 | 4/23/2012 | ML12114A358 | Yes | Confirmatory Action |
| 86 | 1143 | 09.01.02-20 | Poehler, Jeffrey | 9/19/2008 | ML082790092 | 1/21/2009 | ML090210803 | Yes | Resolved - Closed |
| 86 | 1143 | 09.01.02-21 | Poehler, Jeffrey | 9/19/2008 | ML082790092 | 12/19/2008 | ML083540586 | Yes | Resolved - Closed |
| 185 | 2097 | 09.01.02-24 | Poehler, Jeffrey | 2/5/2009 | ML090830496 | 4/22/2009 | ML091120823 | Yes | Resolved - Closed |
| 185 | 2097 | 09.01.02-25 | Poehler, Jeffrey | 2/5/2009 | ML090830496 | 4/22/2009 | ML091120823 | Yes | Resolved - Closed |
| 526 | 6190 | 09.01.02-40 | Hernandez, Raul | 11/11/2011 | ML12013A039 | 5/15/2013 | ML13136A147 | Yes | In Evaluation |
| 526 | 6190 | 09.01.02-41 | Hernandez, Raul | 11/11/2011 | ML12013A039 | 5/23/2013 | ML13144A089 | Yes | In Evaluation |
| 595 | 7203 | 09.01.02-42 | Hernandez, Raul | 8/14/2013 | | | | Yes | Issued/Waiting for Response |
| 526 | 6191 | 09.01.03-14 | Hernandez, Raul | 11/11/2011 | ML12013A039 | 5/15/2013 | ML13136A147 | Yes | In Evaluation |
| 526 | 6191 | 09.01.03-15 | Hernandez, Raul | 11/11/2011 | ML12013A039 | 2/22/2013 | ML13065A139 | Yes | In Evaluation |
| 550 | 6501 | 09.01.03-16 | Hernandez, Raul | 5/18/2012 | ML12147A003 | 10/25/2012 | ML12299A836 | Yes | Confirmatory Action |
| 513 | 6040 | 09.01.04-20 | Nolan, Ryan | 9/13/2011 | ML11273A171 | 3/20/2013 | ML13080A131 | Yes | Resolved - Closed |
| 525 | 6194 | 09.01.04-21 | Curran, Gordon | 11/11/2011 | ML11353A506 | 2/28/2013 | ML13066A012 | Yes | Confirmatory Action |
| 525 | 6194 | 09.01.04-22 | Curran, Gordon | 11/11/2011 | ML11353A506 | 5/24/2013 | ML13147A002 | Yes | In Evaluation |
| 525 | 6194 | 09.01.04-23 | Curran, Gordon | 11/11/2011 | ML11353A506 | 4/30/2013 | ML13121A114 | Yes | In Evaluation |
| 525 | 6194 | 09.01.04-23 | Curran, Gordon | 11/11/2011 | ML11353A506 | 4/30/2013 | ML13121A115 | Yes | In Evaluation |
| 525 | 6194 | 09.01.04-23 | Curran, Gordon | 11/11/2011 | ML11353A506 | 4/30/2013 | ML13121A119 | Yes | In Evaluation |
| 525 | 6194 | 09.01.04-24 | Curran, Gordon | 11/11/2011 | ML11353A506 | 5/15/2013 | ML13136A148 | Yes | In Evaluation |
| 525 | 6194 | 09.01.04-25 | Curran, Gordon | 11/11/2011 | ML11353A506 | 5/15/2013 | ML13136A148 | Yes | In Evaluation |
| 525 | 6194 | 09.01.04-26 | Curran, Gordon | 11/11/2011 | ML11353A506 | 5/15/2013 | ML13136A148 | Yes | In Evaluation |
| 525 | 6194 | 09.01.04-27 | Curran, Gordon | 11/11/2011 | ML11353A506 | 4/30/2013 | ML13121A341 | Yes | In Evaluation |
| 525 | 6194 | 09.01.04-28 | Curran, Gordon | 11/11/2011 | ML11353A506 | 5/30/2012 | ML12152A003 | Yes | In Evaluation |
| 525 | 6154 | 09.01.04-29 | Thomas, George | 11/11/2011 | ML11353A506 | 4/30/2013 | ML13120A757 | Yes | Resolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 525 | 6154 | 09.01.04-30 | Thomas, George | 11/11/2011 | ML11353A506 | 5/15/2013 | ML13136A148 | Yes | Confirmatory Action |
| 525 | 6154 | 09.01.04-31 | Thomas, George | 11/11/2011 | ML11353A506 | 5/31/2013 | ML13154A438 | Yes | Resolved - Closed |
| 525 | 6154 | 09.01.04-32 | Thomas, George | 11/11/2011 | ML11353A506 | 2/25/2013 | ML13066A002 | Yes | Resolved - Closed |
| 525 | 6154 | 09.01.04-33 | Thomas, George | 11/11/2011 | ML11353A506 | 5/24/2013 | ML13147A002 | Yes | Resolved - Closed |
| 525 | 6154 | 09.01.04-34 | Thomas, George | 11/11/2011 | ML11353A506 | 2/28/2013 | ML13066A012 | Yes | Resolved - Closed |
| 525 | 6154 | 09.01.04-35 | Thomas, George | 11/11/2011 | ML11353A506 | 2/25/2013 | ML13066A002 | Yes | Resolved - Closed |
| 525 | 6154 | 09.01.04-36 | Thomas, George | 11/11/2011 | ML11353A506 | 5/24/2013 | ML13147A002 | Yes | Resolved - Closed |
| 525 | 6154 | 09.01.04-37 | Thomas, George | 11/11/2011 | ML11353A506 | 5/24/2013 | ML13147A002 | Yes | Resolved - Closed |
| 525 | 6154 | 09.01.04-38 | Thomas, George | 11/11/2011 | ML11353A506 | | | Yes | Resolved - Closed |
| 534 | 6227 | 09.01.04-39 | Bernal-Taylor, Sara | 12/8/2011 | ML11354A355 | 5/24/2013 | ML13144A811 | Yes | In Evaluation |
| 534 | 6227 | 09.01.04-40 | Bernal-Taylor, Sara | 12/8/2011 | ML11354A355 | 3/16/2012 | ML12077A002 | Yes | Resolved - Closed |
| 536 | 6260 | 09.01.04-41 | Jenkins, Joel | 12/23/2011 | ML12013A041 | 4/11/2012 | ML12102A155 | Yes | Resolved - Closed |
| 621 | 7295 | 09.01.04-42 | Curran, Gordon | 4/14/2014 | ML14104B212 | | | Yes | Issued/Waiting for Response |
| 622 | 7300 | 09.01.04-43 | Stutzcage, Edward | 2/11/2014 | ML14042A262 | | | Yes | Issued/Waiting for Response |
| 628 | 7337 | 09.01.04-44 | Curran, Gordon | 4/14/2014 | ML14104B235 | | | Yes | Issued/Waiting for Response |
| 530 | 6197 | 09.01.05-24 | Curran, Gordon | 11/25/2011 | ML11342A243 | 2/28/2013 | ML13066A014 | Yes | In Evaluation |
| 620 | 7255 | 09.01.05-25 | Curran, Gordon | 2/3/2014 | ML14034A269 | | | Yes | Issued/Waiting for Response |
| 601 | 7225 | 09.02.01-52 | Wheeler, Larry | 11/6/2013 | ML13310C190 | | | Yes | Issued/Waiting for Response |
| 518 | 6122 | 09.02.05-38 | Wheeler, Larry | 10/13/2011 | ML11286A313 | 6/25/2012 | ML12177A423 | Yes | Confirmatory Action |
| 185 | 2085 | 09.03.02-10 | Poehler, Jeffrey | 2/5/2009 | ML090830496 | 4/22/2009 | ML091120823 | Yes | Resolved - Closed |
| 185 | 2085 | 09.03.02-11 | Poehler, Jeffrey | 2/5/2009 | ML090830496 | 4/22/2009 | ML091120823 | Yes | Resolved - Closed |
| 185 | 2085 | 09.03.02-12 | Poehler, Jeffrey | 2/5/2009 | ML090830496 | 4/22/2009 | ML091120823 | Yes | Resolved - Closed |
| 223 | 2678 | 09.03.02-14 | Poehler, Jeffrey | 5/11/2009 | ML091600735 | 7/9/2009 | ML091900766 | Yes | Resolved - Closed |
| 113 | 1284 | 09.03.02-3 | Poehler, Jeffrey | 10/21/2008 | ML083110302 | 12/8/2008 | ML083430814 | Yes | Unresolved - Closed |
| 113 | 1284 | 09.03.02-4 | Poehler, Jeffrey | 10/21/2008 | ML083110302 | 12/8/2008 | ML083430814 | Yes | Resolved - Closed |
| 113 | 1284 | 09.03.02-6 | Poehler, Jeffrey | 10/21/2008 | ML083110302 | 12/8/2008 | ML083430814 | Yes | Unresolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 520 | 6136 | 09.03.03-10 | Dehmel, Jean-Claude | 10/17/2011 | ML11290A256 | 11/16/2011 | ML11321A208 | Yes | Resolved - Closed |
| 476 | 5551 | 09.03.03-7 | Nolan, Ryan | 3/4/2011 | ML110660674 | 6/24/2011 | ML11175A281 | Yes | Resolved - Closed |
| 476 | 5551 | 09.03.03-8 | Nolan, Ryan | 3/4/2011 | ML110660674 | 6/24/2011 | ML11175A281 | Yes | Resolved - Closed |
| 476 | 5551 | 09.03.03-9 | Nolan, Ryan | 3/4/2011 | ML110660674 | 6/24/2011 | ML11175A281 | Yes | Resolved - Closed |
| 125 | 1440 | 09.03.04-15 | Poehler, Jeffrey | 10/24/2008 | ML083110199 | 12/5/2008 | ML083400587 | Yes | Unresolved - Closed |
| 125 | 1440 | 09.03.04-16 | Poehler, Jeffrey | 10/24/2008 | ML083110199 | 12/5/2008 | ML083400587 | Yes | Resolved - Closed |
| 125 | 1440 | 09.03.04-18 | Poehler, Jeffrey | 10/24/2008 | ML083110199 | 12/5/2008 | ML083400587 | Yes | Unresolved - Closed |
| 200 | 2282 | 09.03.04-19 | Poehler, Jeffrey | 3/6/2009 | ML090840027 | 4/24/2009 | ML091170066 | Yes | Unresolved - Closed |
| 200 | 2282 | 09.03.04-20 | Poehler, Jeffrey | 3/6/2009 | ML090840027 | 4/24/2009 | ML091170066 | Yes | Unresolved - Closed |
| 492 | 5815 | 09.03.04-21 | Sastre, Eduardo | 5/21/2011 | ML11155A002 | 4/18/2012 | ML12109A431 | Yes | Unresolved - Closed |
| 492 | 5815 | 09.03.04-22 | Sastre, Eduardo | 5/21/2011 | ML11155A002 | 3/30/2012 | ML12090A213 | Yes | Resolved - Closed |
| 492 | 5815 | 09.03.04-23 | Sastre, Eduardo | 5/21/2011 | ML11155A002 | 8/15/2012 | ML12228A321 | Yes | Resolved - Closed |
| 492 | 5815 | 09.03.04-24 | Sastre, Eduardo | 5/21/2011 | ML11155A002 | 2/15/2012 | ML12047A011 | Yes | Resolved - Closed |
| 492 | 5815 | 09.03.04-25 | Sastre, Eduardo | 5/21/2011 | ML11155A002 | 4/4/2012 | ML12095A244 | Yes | Resolved - Closed |
| 492 | 5815 | 09.03.04-26 | Sastre, Eduardo | 5/21/2011 | ML11155A002 | 3/30/2012 | ML12090A213 | Yes | Resolved - Closed |
| 556 | 6547 | 09.03.04-27 | Sastre, Eduardo | 8/20/2012 | | 3/4/2013 | ML13066A024 | Yes | Resolved - Closed |
| 559 | 6730 | 09.03.04-28 | Sastre, Eduardo | 10/2/2012 | ML12284A028 | | | Yes | Resolved - Closed |
| 277 | 3371 | 09.04.01-1 | ODriscoll, James | 8/17/2009 | ML092590451 | 6/30/2011 | ML11182A003 | Yes | Resolved - Closed |
| 461 | 5223 | 09.04.01-3 | ODriscoll, James | 12/8/2010 | ML110340212 | 9/7/2012 | ML12251A364 | Yes | Resolved - Closed |
| 461 | 5223 | 09.04.01-4 | ODriscoll, James | 12/8/2010 | ML110340212 | 11/18/2011 | ML11325A421 | Yes | Resolved - Closed |
| 461 | 5223 | 09.04.01-5 | ODriscoll, James | 12/8/2010 | ML110340212 | 11/18/2011 | ML11325A421 | Yes | Resolved - Closed |
| 509 | 6011 | 09.04.01-6 | ODriscoll, James | 8/31/2011 | ML11284A248 | 2/8/2012 | ML12046A893 | Yes | Resolved - Closed |
| 509 | 6011 | 09.04.01-7 | ODriscoll, James | 8/31/2011 | ML11284A248 | 2/8/2012 | ML12046A893 | Yes | Resolved - Closed |
| 277 | 3372 | 09.04.02-1 | ODriscoll, James | 8/17/2009 | ML092590451 | 6/30/2011 | ML11182A003 | Yes | Resolved - Closed |
| 277 | 3376 | 09.04.03-2 | ODriscoll, James | 8/17/2009 | ML092590451 | 2/4/2010 | ML100390118 | Yes | Resolved - Closed |
| 461 | 5292 | 09.04.03-4 | ODriscoll, James | 12/8/2010 | ML110340212 | 9/7/2012 | ML12251A364 | Yes | Resolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 461 | 5292 | 09.04.03-5 | ODriscoll, James | 12/8/2010 | ML110340212 | 11/18/2011 | ML11325A421 | Yes | Resolved - Closed |
| 461 | 5292 | 09.04.03-6 | ODriscoll, James | 12/8/2010 | ML110340212 | 9/7/2012 | ML12251A364 | Yes | Resolved - Closed |
| 578 | 7035 | 09.04.03-7 | Goel, Raj | 3/15/2013 | | | | Yes | Issued/Waiting for Response |
| 461 | 5293 | 09.04.05-3 | ODriscoll, James | 12/8/2010 | ML110340212 | 11/18/2011 | ML11325A421 | Yes | Resolved - Closed |
| 461 | 5293 | 09.04.05-4 | ODriscoll, James | 12/8/2010 | ML110340212 | 11/18/2011 | ML11325A421 | Yes | Resolved - Closed |
| 558 | 6720 | 09.04.05-5 | Goel, Raj | 8/31/2012 | | 2/5/2013 | ML13065A125 | Yes | Confirmatory Action |
| 517 | 6052 | 09.05.01-86 | McCann - Disabled 7/15/2012, Edward | 10/1/2011 | ML11284A263 | 4/3/2012 | ML12094A314 | Yes | Resolved - Closed |
| 518 | 6125 | 09.05.01-87 | McCann - Disabled 7/15/2012, Edward | 10/13/2011 | ML11286A313 | 2/27/2012 | ML12061A431 | Yes | Resolved - Closed |
| 519 | 6131 | 09.05.01-88 | McCann - Disabled 7/15/2012, Edward | 10/15/2011 | ML11290A251 | 3/12/2012 | ML12072A296 | Yes | Confirmatory Action |
| **Chapter 10 Total - 23 Question(s) / 23 Response(s)** | | | | | | | | | |
| 294 | 3758 | 10.02.03-17 | Honcharik, John | 9/18/2009 | ML092780721 | 3/26/2012 | ML13058A588 | Yes | Resolved - Closed |
| 294 | 3758 | 10.02.03-18 | Honcharik, John | 9/18/2009 | ML092780721 | 5/19/2011 | ML11140A003 | Yes | Resolved - Closed |
| 294 | 3758 | 10.02.03-19 | Honcharik, John | 9/18/2009 | ML092780721 | 12/15/2011 | ML11349A355 | Yes | Resolved - Closed |
| 294 | 3758 | 10.02.03-20 | Honcharik, John | 9/18/2009 | ML092780721 | 3/26/2012 | ML13058A588 | Yes | Resolved - Closed |
| 294 | 3758 | 10.02.03-21 | Honcharik, John | 9/18/2009 | ML092780721 | 5/19/2011 | ML11140A003 | Yes | Resolved - Closed |
| 294 | 3758 | 10.02.03-22 | Honcharik, John | 9/18/2009 | ML092780721 | 12/15/2011 | ML11349A355 | Yes | Resolved - Closed |
| 294 | 3758 | 10.02.03-23 | Honcharik, John | 9/18/2009 | ML092780721 | 3/26/2012 | ML13058A588 | Yes | Resolved - Closed |
| 430 | 4801 | 10.02-10 | Reddy, Devender | 7/27/2010 | ML102571610 | 4/26/2012 | ML12117A459 | Yes | Resolved - Closed |
| 329 | 3824 | 10.02-7 | Reddy, Devender | 11/16/2009 | ML093200735 | 2/25/2010 | ML100560497 | Yes | Unresolved - Closed |
| 430 | 4801 | 10.02-8 | Reddy, Devender | 7/27/2010 | ML102571610 | 6/9/2011 | ML11160A224 | Yes | Resolved - Closed |
| 430 | 4801 | 10.02-9 | Reddy, Devender | 7/27/2010 | ML102571610 | 4/26/2012 | ML12117A459 | Yes | Resolved - Closed |
| 272 | 3379 | 10.03.06-11 | Davis, Robert | 8/6/2009 | ML092330945 | 9/9/2010 | ML102530242 | Yes | Resolved - Closed |
| 272 | 3379 | 10.03.06-12 | Davis, Robert | 8/6/2009 | ML092330945 | 9/9/2010 | ML102530242 | Yes | Resolved - Closed |
| 62 | 1127 | 10.04.08-1 | Poehler, Jeffrey | 8/27/2008 | ML082790052 | 10/20/2008 | ML082980440 | Yes | Resolved - Closed |
| 610 | 7261 | 10.04.08-10 | Makar, Gregory | 11/6/2013 | ML13310A715 | 5/15/2014 | ML14136A001 | Yes | Confirmatory Action |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 610 | 7261 | 10.04.08-5 | Makar, Gregory | 11/6/2013 | ML13310A715 | 5/15/2014 | ML14136A001 | Yes | Resolved - Closed |
| 610 | 7261 | 10.04.08-6 | Makar, Gregory | 11/6/2013 | ML13310A715 | 5/15/2014 | ML14136A001 | Yes | Resolved - Closed |
| 610 | 7261 | 10.04.08-7 | Makar, Gregory | 11/6/2013 | ML13310A715 | 5/15/2014 | ML14136A001 | Yes | Confirmatory Action |
| 610 | 7261 | 10.04.08-8 | Makar, Gregory | 11/6/2013 | ML13310A715 | 5/15/2014 | ML14136A001 | Yes | Confirmatory Action |
| 610 | 7261 | 10.04.08-9 | Makar, Gregory | 11/6/2013 | ML13310A715 | 5/15/2014 | ML14136A001 | Yes | Confirmatory Action |
| 238 | 2881 | 10.04.09-12 | Stubbs, Angelo | 6/5/2009 | ML091590272 | 10/26/2009 | ML092990652 | Yes | Resolved - Closed |
| 305 | 3804 | 10.04.09-13 | Stubbs, Angelo | 10/5/2009 | ML092860009 | 2/25/2010 | ML100560478 | Yes | Resolved - Closed |
| 605 | 7234 | 10.04.09-14 | Stubbs, Angelo | 10/22/2013 | ML13295A478 | 5/15/2014 | ML14135A541 | Yes | In Evaluation |
| **Chapter 11 Total - 49 Question(s) / 51 Response(s)** | | | | | | | | | |
| 273 | 3450 | 11.02-14 | Tesfaye, Getachew | 8/11/2009 | ML092570706 | 4/11/2011 | ML111010511 | Yes | Resolved - Closed |
| 273 | 3450 | 11.02-15 | Tesfaye, Getachew | 8/11/2009 | ML092570706 | 1/13/2011 | ML093130009 | Yes | Resolved - Closed |
| 299 | 3783 | 11.02-16 | Dehmel, Jean-Claude | 9/23/2009 | ML092790587 | 1/13/2011 | ML100900228 | Yes | Resolved - Closed |
| 301 | 3802 | 11.02-17 | Dehmel, Jean-Claude | 9/24/2009 | ML092790589 | 7/28/2010 | ML102100069 | Yes | Resolved - Closed |
| 359 | 4259 | 11.02-18 | Dehmel, Jean-Claude | 1/22/2010 | ML100601330 | 1/13/2011 | ML101260185 | Yes | Resolved - Closed |
| 387 | 4591 | 11.02-19 | Dehmel, Jean-Claude | 4/6/2010 | ML101020687 | 1/13/2011 | ML101320610 | Yes | Resolved - Closed |
| 387 | 4591 | 11.02-20 | Dehmel, Jean-Claude | 4/6/2010 | ML101020687 | 1/13/2011 | ML102100073 | Yes | Resolved - Closed |
| 387 | 4591 | 11.02-21 | Dehmel, Jean-Claude | 4/6/2010 | ML101020687 | 1/13/2011 | ML102871159 | Yes | Resolved - Closed |
| 405 | 4691 | 11.02-22 | Dehmel, Jean-Claude | 5/14/2010 | ML101460312 | 1/13/2011 | ML102110014 | Yes | Resolved - Closed |
| 405 | 4691 | 11.02-23 | Dehmel, Jean-Claude | 5/14/2010 | ML101460312 | 1/13/2011 | ML102110014 | Yes | Resolved - Closed |
| 405 | 4691 | 11.02-24 | Dehmel, Jean-Claude | 5/14/2010 | ML101460312 | 1/13/2011 | ML102110014 | Yes | Resolved - Closed |
| 423 | 4757 | 11.02-25 | Dehmel, Jean-Claude | 6/17/2010 | ML101740050 | 1/13/2011 | ML102310314 | Yes | Resolved - Closed |
| 436 | 4849 | 11.02-26 | Dehmel, Jean-Claude | 8/17/2010 | ML102390569 | 1/13/2011 | ML103130174 | Yes | Resolved - Closed |
| 554 | 6572 | 11.02-27 | Dehmel, Jean-Claude | 8/1/2012 | | 5/17/2013 | ML13137A487 | Yes | In Evaluation |
| 273 | 3450 | 11.02-5 | Tesfaye, Getachew | 8/11/2009 | ML092570706 | 1/13/2011 | ML093130009 | Yes | Resolved - Closed |
| 273 | 3459 | 11.03-12 | Jennings, Jason | 8/11/2009 | ML092570706 | 4/4/2011 | | Yes | Resolved - Closed |
| 273 | 3459 | 11.03-13 | Jennings, Jason | 8/11/2009 | ML092570706 | 1/13/2011 | ML100900510 | Yes | Resolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 299 | 3784 | 11.03-14 | Dehmel, Jean-Claude | 9/23/2009 | ML092790587 | 1/13/2011 | ML093130005 | Yes | Resolved - Closed |
| 301 | 3803 | 11.03-15 | Dehmel, Jean-Claude | 9/24/2009 | ML092790589 | 1/13/2011 | ML102100069 | Yes | Resolved - Closed |
| 391 | 4595 | 11.03-16 | Dehmel, Jean-Claude | 4/19/2010 | ML101180007 | 1/13/2011 | ML102210466 | Yes | Resolved - Closed |
| 391 | 4643 | 11.03-17 | Dehmel, Jean-Claude | 4/19/2010 | ML101180007 | 1/13/2011 | ML101730588 | Yes | Resolved - Closed |
| 405 | 4724 | 11.03-18 | Dehmel, Jean-Claude | 5/14/2010 | ML101460312 | 7/29/2010 | ML102110014 | Yes | Resolved - Closed |
| 273 | 3460 | 11.04-10 | Jennings, Jason | 8/11/2009 | ML092570706 | 1/13/2011 | ML093130009 | Yes | Resolved - Closed |
| 273 | 3460 | 11.04-11 | Jennings, Jason | 8/11/2009 | ML092570706 | 1/13/2011 | ML092870820 | Yes | Resolved - Closed |
| 273 | 3460 | 11.04-12 | Jennings, Jason | 8/11/2009 | ML092570706 | 1/13/2011 | ML092870820 | Yes | Resolved - Closed |
| 273 | 3460 | 11.04-13 | Jennings, Jason | 8/11/2009 | ML092570706 | 1/13/2011 | ML092870820 | Yes | Resolved - Closed |
| 273 | 3460 | 11.04-15 | Jennings, Jason | 8/11/2009 | ML092570706 | 1/13/2011 | ML101390617 | Yes | Resolved - Closed |
| 391 | 4598 | 11.04-16 | Dehmel, Jean-Claude | 4/19/2010 | ML101180007 | 1/13/2011 | ML101730588 | Yes | Resolved - Closed |
| 273 | 3460 | 11.04-8 | Jennings, Jason | 8/11/2009 | ML092570706 | 1/13/2011 | ML093130009 | Yes | Resolved - Closed |
| 273 | 3462 | 11.05-1 | Jennings, Jason | 8/11/2009 | ML092570706 | 1/13/2011 | ML100900510 | Yes | Resolved - Closed |
| 273 | 3462 | 11.05-10 | Jennings, Jason | 8/11/2009 | ML092570706 | 8/10/2011 | ML11223A007 | Yes | Resolved - Closed |
| 276 | 3496 | 11.05-13 | Dehmel, Jean-Claude | 8/17/2009 | ML092570713 | 1/13/2011 | ML093160550 | Yes | Resolved - Closed |
| 276 | 3496 | 11.05-14 | Dehmel, Jean-Claude | 8/17/2009 | ML092570713 | 1/13/2011 | ML101390618 | Yes | Resolved - Closed |
| 290 | 3637 | 11.05-15 | Dehmel, Jean-Claude | 9/10/2009 | ML092650305 | 1/13/2011 | ML100900534 | Yes | Resolved - Closed |
| 273 | 3462 | 11.05-2 | Dehmel, Jean-Claude | 8/11/2009 | ML092570706 | 8/10/2011 | ML11223A007 | Yes | Confirmatory Action |
| 273 | 3462 | 11.05-2 | Dehmel, Jean-Claude | 8/11/2009 | ML092570706 | 2/15/2013 | ML13065A136 | Yes | Confirmatory Action |
| 346 | 4146 | 11.05-20 | Dehmel, Jean-Claude | 12/16/2009 | ML093511010 | 1/13/2011 | ML100910401 | Yes | Resolved - Closed |
| 392 | 4650 | 11.05-21 | Dehmel, Jean-Claude | 4/28/2010 | ML101600055 | 1/13/2011 | ML102590036 | Yes | Resolved - Closed |
| 405 | 4674 | 11.05-22 | Dehmel, Jean-Claude | 5/14/2010 | ML101460312 | 1/13/2011 | ML102110014 | Yes | Resolved - Closed |
| 405 | 4674 | 11.05-23 | Dehmel, Jean-Claude | 5/14/2010 | ML101460312 | 7/29/2010 | ML102110014 | Yes | Resolved - Closed |
| 405 | 4674 | 11.05-24 | Dehmel, Jean-Claude | 5/14/2010 | ML101460312 | 8/10/2011 | ML11223A008 | Yes | Resolved - Closed |
| 405 | 4674 | 11.05-25 | Dehmel, Jean-Claude | 5/14/2010 | ML101460312 | 1/13/2011 | ML102110014 | Yes | Resolved - Closed |
| 436 | 4968 | 11.05-26 | Dehmel, Jean-Claude | 8/17/2010 | ML102390569 | 1/13/2011 | ML102950439 | Yes | Resolved - Closed |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 436 | 4968 | 11.05-27 | Dehmel, Jean-Claude | 8/17/2010 | ML102390569 | 1/13/2011 | ML102950439 | Yes | Resolved - Closed |
| 528 | 6177 | 11.05-28 | Dehmel, Jean-Claude | 11/25/2011 | ML11350A068 | | | Yes | Unresolved - Closed |
| 625 | 7387 | 11.05-29 | Dehmel, Jean-Claude | 3/11/2014 | ML14076A103 | | | Yes | Issued/Waiting for Response |
| 273 | 3462 | 11.05-5 | Jennings, Jason | 8/11/2009 | ML092570706 | 8/10/2011 | ML11223A007 | Yes | In Evaluation |
| 273 | 3462 | 11.05-5 | Jennings, Jason | 8/11/2009 | ML092570706 | 2/15/2013 | ML13065A136 | Yes | In Evaluation |
| 273 | 3462 | 11.05-7 | Jennings, Jason | 8/11/2009 | ML092570706 | 8/10/2011 | ML11223A007 | Yes | Resolved - Closed |
| 273 | 3462 | 11.05-8 | Jennings, Jason | 8/11/2009 | ML092570706 | 8/10/2011 | ML11223A007 | Yes | Resolved - Closed |
| 273 | 3462 | 11.05-9 | Jennings, Jason | 8/11/2009 | ML092570706 | 8/10/2011 | ML11223A007 | Yes | Resolved - Closed |
| **Chapter 12 Total - 27 Question(s) / 27 Response(s)** | | | | | | | | | |
| 280 | 3307 | 12.02-5 | Bernal-Taylor, Sara | 8/25/2009 | ML092390592 | 5/13/2010 | ML101330610 | Yes | Resolved - Closed |
| 280 | 3307 | 12.02-6 | Bernal-Taylor, Sara | 8/25/2009 | ML092390592 | 5/13/2010 | ML101330610 | Yes | Resolved - Closed |
| 627 | 7408 | 12.02-7 | Stutzcage, Edward | 2/10/2014 | ML14041A483 | | | Yes | Issued/Waiting for Response |
| 23 | 460 | 12.03-12.04-1 | Bernal-Taylor, Sara | 6/19/2008 | ML081760690 | 12/3/2009 | ML093390005 | Yes | Unresolved - Closed |
| 228 | 2755 | 12.03-12.04-10 | Bernal-Taylor, Sara | 5/15/2009 | ML091590270 | 8/27/2009 | ML092390664 | Yes | Unresolved - Closed |
| 254 | 3052 | 12.03-12.04-15 | Bernal-Taylor, Sara | 6/18/2009 | ML091770351 | 9/10/2009 | ML092540011 | Yes | Resolved - Closed |
| 267 | 3234 | 12.03-12.04-16 | Peng, Shie-Jeng | 8/3/2009 | ML092530631 | 3/22/2010 | ML100900231 | Yes | Resolved - Closed |
| 280 | 3554 | 12.03-12.04-17 | Bernal-Taylor, Sara | 8/25/2009 | ML092390592 | 3/16/2011 | ML110750764 | Yes | Unresolved - Closed |
| 295 | 3761 | 12.03-12.04-18 | Bernal-Taylor, Sara | 9/18/2009 | ML092650826 | 5/12/2010 | ML101330018 | Yes | Unresolved - Closed |
| 296 | 3710 | 12.03-12.04-19 | Bernal-Taylor, Sara | 9/22/2009 | ML092650802 | 2/19/2010 | ML100500847 | Yes | Resolved - Closed |
| 360 | 4132 | 12.03-12.04-20 | Bernal-Taylor, Sara | 1/22/2010 | ML100630799 | 7/12/2010 | ML101930466 | Yes | Unresolved - Closed |
| 360 | 4132 | 12.03-12.04-21 | Bernal-Taylor, Sara | 1/22/2010 | ML100630799 | 5/11/2011 | ML11131A083 | Yes | Resolved - Closed |
| 424 | 4789 | 12.03-12.04-22 | Bernal-Taylor, Sara | 6/17/2010 | ML101740428 | 12/11/2010 | ML103530002 | Yes | Unresolved - Closed |
| 438 | 4907 | 12.03-12.04-23 | Bernal-Taylor, Sara | 8/18/2010 | ML102390570 | 10/11/2010 | ML102840003 | Yes | Resolved - Closed |
| 446 | 4916 | 12.03-12.04-24 | Bernal-Taylor, Sara | 9/16/2010 | ML102670272 | 10/15/2010 | ML102880653 | Yes | Resolved - Closed |
| 459 | 5253 | 12.03-12.04-25 | Bernal-Taylor, Sara | 12/4/2010 | ML103550263 | 3/29/2012 | ML12089A488 | Yes | Unresolved - Closed |
| 459 | 5253 | 12.03-12.04-26 | Bernal-Taylor, Sara | 12/4/2010 | ML103550263 | 4/11/2011 | ML110020709 | Yes | Resolved - Closed |

# eRAI Question Status Report
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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 470 | 5397 | 12.03-12.04-27 | Bernal-Taylor, Sara | 1/25/2011 | ML110320634 | 4/11/2011 | ML111010514 | Yes | Resolved - Closed |
| 529 | 6178 | 12.03-12.04-28 | Dehmel, Jean-Claude | 11/25/2011 | ML11342A241 | | | Yes | Issued/Waiting for Response |
| 539 | 6259 | 12.03-12.04-29 | Stutzcage, Edward | 1/19/2012 | ML12031A065 | | | Yes | Issued/Waiting for Response |
| 548 | 6469 | 12.03-12.04-30 | Stutzcage, Edward | 5/17/2012 | ML12179A536 | 11/27/2012 | ML12333A375 | Yes | Unresolved - Closed |
| 548 | 6469 | 12.03-12.04-31 | Stutzcage, Edward | 5/17/2012 | ML12179A536 | 11/27/2012 | ML12333A375 | Yes | Issued/Waiting for Response |
| 228 | 2755 | 12.03-12.04-9 | Bernal-Taylor, Sara | 5/15/2009 | ML091590270 | 8/27/2009 | ML092390664 | Yes | Unresolved - Closed |
| 593 | 7172 | 12.03-33 | Stutzcage, Edward | 7/11/2013 | | | | Yes | Issued/Waiting for Response |
| 599 | 7224 | 12.03-34 | Stutzcage, Edward | 11/6/2013 | ML13310C166 | | | Yes | Issued/Waiting for Response |
| 616 | 7267 | 12.03-35 | Stutzcage, Edward | 11/26/2013 | ML13330B674 | | | Yes | Issued/Waiting for Response |
| 302 | 3830 | 12.05-3 | Bernal-Taylor, Sara | 10/2/2009 | ML092750649 | 2/19/2010 | ML100500841 | Yes | Resolved - Closed |
| **Chapter 13 Total - 4 Question(s) / 5 Response(s)** | | | | | | | | | |
| 549 | 6524 | 13.03-8 | Swain, Patricia | 5/18/2012 | ML12147A002 | 9/14/2012 | ML12258A473 | Yes | Resolved - Closed |
| 549 | 6524 | 13.03-8 | Swain, Patricia | 5/18/2012 | ML12147A002 | 3/8/2013 | ML13067A249 | Yes | Resolved - Closed |
| 425 | 4799 | 13.06.02-1 | Lee, Pete | 6/22/2010 | ML102080489 | 11/8/2011 | ML11312A325 | Yes | Resolved - Closed |
| 425 | 4799 | 13.06.02-2 | Lee, Pete | 6/22/2010 | ML102080489 | 11/8/2011 | ML11312A325 | Yes | Resolved - Closed |
| 425 | 4799 | 13.06.02-4 | Lee, Pete | 6/22/2010 | ML102080489 | 11/8/2011 | ML11312A325 | Yes | Resolved - Closed |
| **Chapter 14 Total - 47 Question(s) / 49 Response(s)** | | | | | | | | | |
| 386 | 4418 | 14.02-156 | Dehmel, Jean-Claude | 4/6/2010 | ML101241158 | 8/10/2011 | ML11223A011 | Yes | Unresolved - Closed |
| 386 | 4418 | 14.02-158 | Dehmel, Jean-Claude | 4/6/2010 | ML101241158 | 8/10/2011 | ML11223A011 | Yes | Unresolved - Closed |
| 386 | 4418 | 14.02-159 | Dehmel, Jean-Claude | 4/6/2010 | ML101241158 | 8/10/2011 | ML11223A011 | Yes | Unresolved - Closed |
| 527 | 6179 | 14.02-163 | Dehmel, Jean-Claude | 11/25/2011 | ML11350A067 | | | Yes | Unresolved - Closed |
| 613 | 7185 | 14.02-164 | Keim, Andrea | 1/17/2014 | ML14017A190 | | | Yes | Issued/Waiting for Response |
| 127 | 1250 | 14.02-56 | Willis, Dori | 10/27/2008 | ML083171040 | 4/28/2009 | ML091190042 | Yes | Resolved - Closed |
| 176 | 1883 | 14.02-92 | Crane, Samantha | 1/14/2009 | ML090210019 | 5/12/2009 | ML091350076 | Yes | Unresolved - Closed |
| 260 | 3181 | 14.03.02-42 | Jeng, David | 7/14/2009 | ML092170539 | | | Yes | Resolved - Closed |
| 386 | 4349 | 14.03.02-44 | Jeng, David | 4/6/2010 | ML101241158 | 8/29/2011 | ML11241A230 | Yes | Unresolved - Closed |

# eRAI Question Status Report
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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 386 | 4349 | 14.03.02-45 | Jeng, David | 4/6/2010 | ML101241158 | 8/29/2011 | ML11241A230 | Yes | Unresolved - Closed |
| 386 | 4349 | 14.03.02-49 | Jeng, David | 4/6/2010 | ML101241158 | 8/29/2011 | ML11241A230 | Yes | Unresolved - Closed |
| 386 | 4349 | 14.03.02-51 | Jeng, David | 4/6/2010 | ML101241158 | 8/29/2011 | ML11241A230 | Yes | Unresolved - Closed |
| 499 | 5890 | 14.03.02-52 | Chakravorty, Manas | 7/18/2011 | ML11220A005 | 9/30/2011 | ML11273A186 | Yes | Unresolved - Closed |
| 499 | 5890 | 14.03.02-53 | Chakravorty, Manas | 7/18/2011 | ML11220A005 | 9/30/2011 | ML11273A186 | Yes | Unresolved - Closed |
| 499 | 5890 | 14.03.02-54 | Chakravorty, Manas | 7/18/2011 | ML11220A005 | 9/30/2011 | ML11273A186 | Yes | Resolved - Closed |
| 499 | 5890 | 14.03.02-55 | Chakravorty, Manas | 7/18/2011 | ML11220A005 | 9/30/2011 | ML11273A186 | Yes | Unresolved - Closed |
| 527 | 6205 | 14.03.02-56 | Chakravorty, Manas | 11/25/2011 | ML11350A067 | | | Yes | Issued/Waiting for Response |
| 527 | 6205 | 14.03.02-57 | Chakravorty, Manas | 11/25/2011 | ML11350A067 | 3/29/2013 | ML13088A308 | Yes | Resolved - Closed |
| 527 | 6205 | 14.03.02-58 | Chakravorty, Manas | 11/25/2011 | ML11350A067 | 3/29/2013 | ML13088A308 | Yes | Issued/Waiting for Response |
| 527 | 6205 | 14.03.02-59 | Chakravorty, Manas | 11/25/2011 | ML11350A067 | 3/29/2013 | ML13088A308 | Yes | Resolved - Closed |
| 527 | 6205 | 14.03.02-60 | Chakravorty, Manas | 11/25/2011 | ML11350A067 | 3/29/2013 | ML13088A308 | Yes | Resolved - Closed |
| 527 | 6205 | 14.03.02-61 | Chakravorty, Manas | 11/25/2011 | ML11350A067 | 3/29/2013 | ML13088A608 | Yes | Resolved - Closed |
| 527 | 6205 | 14.03.02-62 | Chakravorty, Manas | 11/25/2011 | ML11350A067 | 5/28/2013 | ML13148A505 | Yes | Resolved - Closed |
| 592 | 7149 | 14.03.02-63 | Chakravorty, Manas | 7/11/2013 | | 9/2/2013 | ML13252A261 | Yes | Resolved - Closed |
| 307 | 3777 | 14.03.03-45 | Ng, Ching | 10/9/2009 | ML092990197 | 3/17/2010 | ML100770004 | Yes | Resolved - Closed |
| 386 | 4512 | 14.03.03-46 | Ng, Ching | 4/6/2010 | ML101241158 | 5/6/2011 | ML11126A237 | Yes | Resolved - Closed |
| 411 | 4734 | 14.03.03-49 | Tseng, Ian | 5/25/2010 | ML101620139 | 6/7/2011 | ML11158A267 | Yes | Issued/Waiting for Response |
| 411 | 4734 | 14.03.03-49 | Tseng, Ian | 5/25/2010 | ML101620139 | 7/20/2012 | ML12202B123 | Yes | Issued/Waiting for Response |
| 501 | 5934 | 14.03.03-53 | Scarbrough, Thomas | 7/21/2011 | ML11242A205 | 9/29/2011 | ML11272A222 | Yes | Resolved - Closed |
| 577 | 7022 | 14.03.03-54 | Scarbrough, Thomas | 3/21/2013 | ML13080A402 | 5/9/2013 | ML13130A018 | Yes | Confirmatory Action |
| 577 | 7022 | 14.03.03-54 | Scarbrough, Thomas | 3/21/2013 | ML13080A402 | 4/19/2013 | ML13109A527 | Yes | Confirmatory Action |
| 506 | 5456 | 14.03.05-25 | Mills, Daniel | 8/12/2011 | ML11242A161 | 11/8/2011 | ML11312A323 | Yes | Unresolved - Closed |
| 506 | 5456 | 14.03.05-27 | Mills, Daniel | 8/12/2011 | ML11242A161 | 3/7/2012 | ML12102A049 | Yes | Resolved - Closed |
| 506 | 5456 | 14.03.05-30 | Mills, Daniel | 8/12/2011 | ML11242A161 | 3/15/2012 | ML12075A243 | Yes | Resolved - Closed |
| 506 | 5456 | 14.03.05-39 | Mills, Daniel | 8/12/2011 | ML11242A161 | 5/30/2012 | ML12152A005 | Yes | Resolved - Closed |

# eRAI Question Status Report
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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 506 | 5456 | 14.03.05-41 | Mills, Daniel | 8/12/2011 | ML11242A161 | 3/15/2012 | ML12075A243 | Yes | Resolved - Closed |
| 615 | 7284 | 14.03.05-43 | Spaulding, Deirdre | 11/6/2013 | ML13310A785 | | | Yes | Issued/Waiting for Response |
| 527 | 6180 | 14.03.07-38 | Dehmel, Jean-Claude | 11/25/2011 | ML11350A067 | | | Yes | Issued/Waiting for Response |
| 557 | 6690 | 14.03.07-39 | Dehmel, Jean-Claude | 8/23/2012 | | | | Yes | Issued/Waiting for Response |
| 386 | 4341 | 14.03.08-2 | Bernal-Taylor, Sara | 4/6/2010 | ML101241158 | 8/10/2011 | ML11223A011 | Yes | Unresolved - Closed |
| 543 | 6323 | 14.03.08-4 | Stutzcage, Edward | 4/5/2012 | ML12110A238 | | | Yes | Resolved - Closed |
| 543 | 6323 | 14.03.08-5 | Stutzcage, Edward | 4/5/2012 | ML12110A238 | 8/16/2012 | ML12230A032 | Yes | Unresolved - Closed |
| 562 | 6825 | 14.03.08-6 | Stutzcage, Edward | 10/2/2012 | ML13010A575 | 5/28/2013 | ML13148A506 | Yes | Issued/Waiting for Response |
| 516 | 6044 | 14.03.09-17 | Pieringer, Paul | 9/28/2011 | ML11284A262 | 3/9/2012 | ML12069A405 | Yes | Resolved - Closed |
| 516 | 6044 | 14.03.09-18 | Pieringer, Paul | 9/28/2011 | ML11284A262 | 3/9/2012 | ML12069A405 | Yes | Resolved - Closed |
| 516 | 6044 | 14.03.09-19 | Pieringer, Paul | 9/28/2011 | ML11284A262 | 3/9/2012 | ML12069A405 | Yes | Resolved - Closed |
| 411 | 4721 | 14.03.11-4 | Grady, Anne-Marie | 5/25/2010 | ML101620139 | 4/5/2011 | ML110960892 | Yes | Resolved - Closed |
| 491 | 5795 | 14.03.12-58 | Lee, Pete | 5/16/2011 | ML11155A003 | 2/6/2012 | ML12037A246 | Yes | Resolved - Closed |
| 469 | 5336 | 14.03-16 | Cheung, Calvin | 1/6/2011 | ML110250668 | 7/19/2013 | ML13202A003 | Yes | Unresolved - Closed |
| **Chapter 15 Total - 20 Question(s) / 20 Response(s)** | | | | | | | | | |
| 432 | 4958 | 15.00.02-1 | Lu, Shanlai | 8/6/2010 | ML102280240 | 6/29/2011 | ML11181A261 | Yes | Resolved - Closed |
| 137 | 1348 | 15.00.03-33 | Poehler, Jeffrey | 11/6/2008 | ML083380113 | 1/28/2009 | ML090280312 | Yes | Unresolved - Closed |
| 137 | 1348 | 15.00.03-35 | Poehler, Jeffrey | 11/6/2008 | ML083380113 | 1/28/2009 | ML090280312 | Yes | Unresolved - Closed |
| 394 | 4663 | 15.00.03-37 | Makar, Gregory | 4/28/2010 | ML101310564 | 7/14/2010 | ML101950415 | Yes | Resolved - Closed |
| 394 | 4663 | 15.00.03-38 | Makar, Gregory | 4/28/2010 | ML101310564 | 7/14/2010 | ML101950415 | Yes | Resolved - Closed |
| 521 | 6147 | 15.00.03-39 | Makar, Gregory | 10/26/2011 | ML11307A542 | | | Yes | Resolved - Closed |
| 493 | 5810 | 15.06.05-100 | Forsaty, Fred | 6/3/2011 | ML11209B015 | 11/18/2011 | ML11325A380 | Yes | Resolved - Closed |
| 493 | 5810 | 15.06.05-113 | Forsaty, Fred | 6/3/2011 | ML11209B015 | 11/16/2011 | ML11321A316 | Yes | Resolved - Closed |
| 573 | 7023 | 15.06.05-116 | Lu, Shanlai | 2/28/2013 | ML13059A048 | | | Yes | Issued/Waiting for Response |
| 573 | 7023 | 15.06.05-117 | Lu, Shanlai | 2/28/2013 | ML13059A048 | 6/13/2013 | ML13164A345 | Yes | Resolved - Closed |
| 403 | 4439 | 15.06.05-61 | Forsaty, Fred | 5/7/2010 | ML101530013 | 7/18/2013 | ML13205A131 | Yes | Resolved - Closed |

# eRAI Question Status Report
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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 403 | 4439 | 15.06.05-62 | Forsaty, Fred | 5/7/2010 | ML101530013 | 7/18/2013 | ML13205A131 | Yes | Resolved - Closed |
| 403 | 4439 | 15.06.05-63 | Forsaty, Fred | 5/7/2010 | ML101530013 | 7/18/2013 | ML13205A131 | Yes | Resolved - Closed |
| 403 | 4439 | 15.06.05-66 | Forsaty, Fred | 5/7/2010 | ML101530013 | 3/9/2012 | ML12074A198 | Yes | Resolved - Closed |
| 403 | 4439 | 15.06.05-68 | Forsaty, Fred | 5/7/2010 | ML101530013 | 3/9/2012 | ML12074A198 | Yes | Resolved - Closed |
| 403 | 4439 | 15.06.05-70 | Forsaty, Fred | 5/7/2010 | ML101530013 | 3/9/2012 | ML12074A198 | Yes | Resolved - Closed |
| 493 | 5810 | 15.06.05-98 | Forsaty, Fred | 6/3/2011 | ML11209B015 | 11/18/2011 | ML11325A380 | Yes | Resolved - Closed |
| 493 | 5810 | 15.06.05-99 | Forsaty, Fred | 6/3/2011 | ML11209B015 | 11/18/2011 | ML11325A380 | Yes | Resolved - Closed |
| 582 | 7069 | 15.08-1 | Budzynski, John | 6/13/2013 | ML13252A262 | 11/11/2013 | ML13316C467 | Yes | In Evaluation |
| 415 | 4599 | 15-9 | Liang, Chu-Yu | 6/8/2010 | ML102070480 | 8/25/2010 | ML102370896 | Yes | Resolved - Closed |
| **Chapter 16 Total - 39 Question(s) / 45 Response(s)** | | | | | | | | | |
| 101 | 931 | 16-102 | Le, Hien | 10/16/2008 | ML083171050 | 12/12/2008 | ML083470962 | Yes | Unresolved - Closed |
| 103 | 1270 | 16-197 | DeMarshall, Joseph | 10/20/2008 | ML083110134 | 11/26/2008 | ML083380062 | Yes | Unresolved - Closed |
| 110 | 1295 | 16-230 | Le, Hien | 10/20/2008 | ML083020340 | 12/1/2008 | ML083380089 | Yes | Unresolved - Closed |
| 110 | 1295 | 16-232 | Le, Hien | 10/20/2008 | ML083020340 | 12/1/2008 | ML083380089 | Yes | Unresolved - Closed |
| 166 | 1481 | 16-291 | Hearn, Peter | 1/6/2009 | ML090090786 | 3/26/2009 | ML090850674 | Yes | Unresolved - Closed |
| 293 | 3713 | 16-294 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-295 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-296 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-297 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-299 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-300 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-301 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-302 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-303 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-304 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-305 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |

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# For use by Project Manager

| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 293 | 3713 | 16-306 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-307 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-308 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 293 | 3713 | 16-309 | Le, Hien | 9/11/2009 | ML092990156 | 7/14/2010 | ML101950417 | Yes | Resolved - Closed |
| 300 | 3730 | 16-310 | Le, Hien | 9/23/2009 | ML093230886 | 3/26/2010 | ML100880004 | Yes | Resolved - Closed |
| 300 | 3742 | 16-311 | Harbuck, Craig | 9/23/2009 | ML093230886 | | | Yes | Issued/Waiting for Response |
| 300 | 3742 | 16-312 | Harbuck, Craig | 9/23/2009 | ML093230886 | 10/7/2010 | ML102800432 | Yes | Issued/Waiting for Response |
| 300 | 3742 | 16-313 | Le, Hien | 9/23/2009 | ML093230886 | 9/16/2011 | ML11262A363 | Yes | Resolved - Closed |
| 300 | 3742 | 16-313 | Le, Hien | 9/23/2009 | ML093230886 | 10/7/2010 | ML102800432 | Yes | Resolved - Closed |
| 300 | 3742 | 16-313 | Le, Hien | 9/23/2009 | ML093230886 | 6/15/2011 | ML11167A088 | Yes | Resolved - Closed |
| 300 | 3742 | 16-313 | Le, Hien | 9/23/2009 | ML093230886 | 4/15/2011 | ML11105A100 | Yes | Resolved - Closed |
| 300 | 3742 | 16-313 | Le, Hien | 9/23/2009 | ML093230886 | 2/8/2011 | ML110400161 | Yes | Resolved - Closed |
| 300 | 3742 | 16-314 | Le, Hien | 9/23/2009 | ML093230886 | 10/7/2010 | ML102800432 | Yes | Resolved - Closed |
| 300 | 3742 | 16-315 | Harbuck, Craig | 9/23/2009 | ML093230886 | 3/26/2010 | ML100880004 | Yes | Issued/Waiting for Response |
| 311 | 3839 | 16-316 | Harbuck, Craig | 10/9/2009 | ML092860028 | 11/3/2010 | ML103090116 | Yes | Resolved - Closed |
| 311 | 3846 | 16-317 | Le, Hien | 10/9/2009 | ML092860028 | 10/21/2010 | ML102950052 | Yes | Resolved - Closed |
| 315 | 3878 | 16-318 | Le, Hien | 10/21/2009 | ML093221046 | 11/1/2011 | ML11305A270 | Yes | Unresolved - Closed |
| 315 | 3878 | 16-318 | Le, Hien | 10/21/2009 | ML093221046 | 3/31/2011 | ML110900652 | Yes | Unresolved - Closed |
| 315 | 3878 | 16-319 | Le, Hien | 10/21/2009 | ML093221046 | 3/31/2011 | ML110900652 | Yes | Unresolved - Closed |
| 315 | 3878 | 16-319 | Le, Hien | 10/21/2009 | ML093221046 | 3/31/2011 | ML110900652 | Yes | Unresolved - Closed |
| 315 | 3878 | 16-320 | Harbuck, Craig | 10/21/2009 | ML093221046 | | | Yes | Issued/Waiting for Response |
| 315 | 3878 | 16-321 | Harbuck, Craig | 10/21/2009 | ML093221046 | 10/12/2010 | ML12251A737 | Yes | Resolved - Closed |
| 484 | 5724 | 16-322 | Harbuck, Craig | 4/20/2011 | ML11115A182 | | | Yes | Issued/Waiting for Response |
| 606 | 7244 | 16-324 | Le, Hien | 9/19/2013 | ML14114A346 | 5/15/2014 | ML14135A544 | Yes | Confirmatory Action |
| 607 | 7246 | 16-325 | Le, Hien | 11/6/2013 | ML13310A690 | | | Yes | Issued/Waiting for Response |
| 618 | 7245 | 16-326 | Le, Hien | 2/3/2014 | ML14034A260 | | | Yes | Issued/Waiting for Response |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 619 | 7247 | 16-327 | Le, Hien | 2/3/2014 | ML14034A263 | | | Yes | Issued/Waiting for Response |
| 101 | 931 | 16-90 | Le, Hien | 10/16/2008 | ML083171050 | 12/12/2008 | ML083470962 | Yes | Unresolved - Closed |
| 101 | 931 | 16-93 | Le, Hien | 10/16/2008 | ML083171050 | 12/12/2008 | ML083470962 | Yes | Unresolved - Closed |
| **Chapter 17 Total - 2 Question(s) / 2 Response(s)** | | | | | | | | | |
| 355 | 4263 | 17.04-23 | Phan, Hanh | 1/9/2010 | ML100110346 | 5/17/2011 | ML11137A203 | Yes | Resolved - Closed |
| 327 | 3988 | 17.5-2 | Kavanagh, Kerri | 11/5/2009 | ML093090724 | 12/4/2009 | ML093390003 | Yes | Resolved - Closed |
| **Chapter 18 Total - 4 Question(s) / 4 Response(s)** | | | | | | | | | |
| 545 | 6417 | 18-239 | Bongarra, James | 4/11/2012 | ML12110A172 | 9/4/2012 | ML12249A080 | Yes | Resolved - Closed |
| 586 | 7124 | 18-240 | Bongarra, James | 8/23/2013 | | | | Yes | Issued/Waiting for Response |
| 586 | 7124 | 18-241 | Bongarra, James | 8/23/2013 | | | | Yes | Issued/Waiting for Response |
| 617 | 7265 | 18-242 | Bongarra, James | 11/14/2013 | ML13318B493 | | | Yes | Issued/Waiting for Response |
| **Chapter 19 Total - 70 Question(s) / 72 Response(s)** | | | | | | | | | |
| 561 | 6504 | 19.01-48 | Pohida, Marie | 1/11/2013 | ML13011A283 | 4/9/2013 | ML13121A354 | Yes | Resolved - Closed |
| 561 | 6504 | 19.01-49 | Pohida, Marie | 1/11/2013 | ML13011A283 | 4/9/2013 | ML13121A354 | Yes | Resolved - Closed |
| 561 | 6504 | 19.01-50 | Pohida, Marie | 1/11/2013 | ML13011A283 | 4/9/2013 | ML13121A354 | Yes | Resolved - Closed |
| 623 | 7304 | 19.02-1 | Law, Yiu | 2/6/2014 | ML14037A499 | | | Yes | Issued/Waiting for Response |
| 133 | 1456 | 19-243 | Grady, Anne-Marie | 10/29/2008 | ML083120545 | 6/19/2009 | ML091700655 | Yes | Resolved - Closed |
| 138 | 1598 | 19-257 | Clark, Theresa | 11/19/2008 | ML083280064 | 12/19/2008 | ML083590360 | Yes | Unresolved - Closed |
| 197 | 2202 | 19-274 | Clark, Theresa | 3/11/2009 | ML090701027 | 4/10/2009 | ML091050349 | Yes | Unresolved - Closed |
| 197 | 2202 | 19-279 | Clark, Theresa | 3/11/2009 | ML090701027 | 9/1/2009 | ML092440842 | Yes | Unresolved - Closed |
| 227 | 2564 | 19-284 | Phan, Hanh | 6/5/2009 | ML091560529 | 12/16/2009 | ML093580056 | Yes | Unresolved - Closed |
| 227 | 2564 | 19-287 | Phan, Hanh | 6/5/2009 | ML091560529 | 12/16/2009 | ML093580056 | Yes | Unresolved - Closed |
| 227 | 2564 | 19-292 | Phan, Hanh | 6/5/2009 | ML091560529 | 12/16/2009 | ML093580056 | Yes | Unresolved - Closed |
| 227 | 2564 | 19-293 | Phan, Hanh | 6/5/2009 | ML091560529 | 9/17/2009 | ML092600981 | Yes | Unresolved - Closed |
| 227 | 2564 | 19-294 | Phan, Hanh | 6/5/2009 | ML091560529 | 9/17/2009 | ML092600981 | Yes | Unresolved - Closed |
| 227 | 2564 | 19-295 | Phan, Hanh | 6/5/2009 | ML091560529 | 9/17/2009 | ML092600981 | Yes | Unresolved - Closed |

# eRAI Question Status Report
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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 227 | 2564 | 19-298 | Phan, Hanh | 6/5/2009 | ML091560529 | 8/27/2009 | ML092390596 | Yes | Resolved - Closed |
| 234 | 2861 | 19-304 | Thomas, George | 6/12/2009 | ML091630256 | 11/5/2009 | ML093090726 | Yes | Unresolved - Closed |
| 234 | 2861 | 19-305 | Thomas, George | 6/12/2009 | ML091630256 | 10/30/2009 | ML093030693 | Yes | Unresolved - Closed |
| 234 | 2861 | 19-306 | Thomas, George | 6/12/2009 | ML091630256 | 10/30/2009 | ML093030693 | Yes | Unresolved - Closed |
| 262 | 3292 | 19-319 | Grady, Anne-Marie | 7/30/2009 | ML092110814 | 10/28/2009 | ML093070073 | Yes | Resolved - Closed |
| 262 | 3292 | 19-320 | Grady, Anne-Marie | 7/30/2009 | ML092110814 | 10/28/2009 | ML093070073 | Yes | Resolved - Closed |
| 262 | 3292 | 19-321 | Grady, Anne-Marie | 7/30/2009 | ML092110814 | 10/12/2009 | ML092890085 | Yes | Resolved - Closed |
| 262 | 3292 | 19-322 | Grady, Anne-Marie | 7/30/2009 | ML092110814 | 10/28/2009 | ML093070073 | Yes | Resolved - Closed |
| 262 | 3292 | 19-323 | Grady, Anne-Marie | 7/30/2009 | ML092110814 | 10/12/2009 | ML092890085 | Yes | Resolved - Closed |
| 262 | 3292 | 19-324 | Grady, Anne-Marie | 7/30/2009 | ML092110814 | 10/12/2009 | ML092890085 | Yes | Resolved - Closed |
| 262 | 3292 | 19-325 | Grady, Anne-Marie | 7/30/2009 | ML092110814 | 8/31/2009 | ML092450721 | Yes | Resolved - Closed |
| 269 | 3448 | 19-327 | Phan, Hanh | 8/6/2009 | ML092330936 | 9/17/2009 | ML092600982 | Yes | Resolved - Closed |
| 289 | 3500 | 19-328 | Phan, Hanh | 8/28/2009 | ML092530158 | | | Yes | In Evaluation |
| 289 | 3500 | 19-329 | Phan, Hanh | 8/28/2009 | ML092530158 | | | Yes | In Evaluation |
| 349 | 4164 | 19-330 | Phan, Hanh | 12/18/2009 | ML100261718 | 4/30/2010 | ML101230007 | Yes | Unresolved - Closed |
| 349 | 4164 | 19-330 | Phan, Hanh | 12/18/2009 | ML100261718 | 1/31/2013 | ML13066A239 | Yes | Unresolved - Closed |
| 349 | 4164 | 19-331 | Phan, Hanh | 12/18/2009 | ML100261718 | 4/30/2010 | ML101230007 | Yes | Unresolved - Closed |
| 349 | 4165 | 19-332 | Grady, Anne-Marie | 1/26/2010 | ML100261718 | 1/26/2010 | ML102700031 | Yes | Resolved - Closed |
| 349 | 4165 | 19-333 | Grady, Anne-Marie | 1/26/2010 | ML100261718 | 1/26/2010 | ML102700031 | Yes | Resolved - Closed |
| 349 | 4165 | 19-334 | Grady, Anne-Marie | 1/26/2010 | ML100261718 | 1/31/2013 | ML13066A239 | Yes | Resolved - Closed |
| 349 | 4165 | 19-335 | Grady, Anne-Marie | 1/26/2010 | ML100261718 | 1/31/2013 | ML13066A239 | Yes | Resolved - Closed |
| 382 | 4539 | 19-336 | Grady, Anne-Marie | 4/29/2010 | ML101190427 | 9/29/2010 | ML102720237 | Yes | Resolved - Closed |
| 396 | 4679 | 19-337 | Xu, Jim | 4/29/2010 | ML101190059 | 7/15/2010 | ML101960401 | Yes | Unresolved - Closed |
| 449 | 5104 | 19-339 | Thomas, George | 12/8/2010 | ML103420248 | 7/6/2011 | ML11188A026 | Yes | Resolved - Closed |
| 449 | 5104 | 19-340 | Thomas, George | 12/8/2010 | ML103420248 | 7/6/2011 | ML11188A026 | Yes | Resolved - Closed |
| 455 | 4911 | 19-341 | Thomas, George | 12/21/2010 | ML103550634 | | | Yes | Issued/Waiting for Response |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 456 | 5150 | 19-342 | McCann - Disabled 7/15/2012, Edward | 1/20/2011 | ML110520003 | 7/6/2011 | ML11188A027 | Yes | Confirmatory Action |
| 456 | 5150 | 19-343 | McCann - Disabled 7/15/2012, Edward | 1/20/2011 | ML110520003 | 7/6/2011 | ML11188A027 | Yes | Confirmatory Action |
| 456 | 5150 | 19-344 | McCann - Disabled 7/15/2012, Edward | 1/20/2011 | ML110520003 | 7/6/2011 | ML11188A027 | Yes | Confirmatory Action |
| 456 | 5150 | 19-345 | McCann - Disabled 7/15/2012, Edward | 1/20/2011 | ML110520003 | 7/6/2011 | ML11188A027 | Yes | Confirmatory Action |
| 456 | 5150 | 19-346 | McCann - Disabled 7/15/2012, Edward | 1/20/2011 | ML110520003 | 7/6/2011 | ML11188A027 | Yes | Resolved - Closed |
| 456 | 5150 | 19-347 | McCann - Disabled 7/15/2012, Edward | 1/20/2011 | ML110520003 | 7/6/2011 | ML11188A027 | Yes | Confirmatory Action |
| 460 | 5153 | 19-348 | Pohida, Marie | 1/6/2011 | ML110060907 | 2/27/2012 | ML12061A427 | Yes | Unresolved - Closed |
| 460 | 5153 | 19-349 | Pohida, Marie | 1/6/2011 | ML110060907 | 2/27/2012 | ML12061A427 | Yes | Unresolved - Closed |
| 460 | 5302 | 19-350 | Grady, Anne-Marie | 1/6/2011 | ML110060907 | | | Yes | Resolved - Closed |
| 495 | 5841 | 19-351 | Xu, Jim | 6/9/2011 | ML11160A230 | | | Yes | Issued/Waiting for Response |
| 532 | 6155 | 19-352 | Grady, Anne-Marie | 12/16/2011 | ML11350A074 | 7/30/2013 | ML13212A377 | Yes | Resolved - Closed |
| 532 | 6155 | 19-352 | Grady, Anne-Marie | 12/16/2011 | ML11350A074 | 1/29/2014 | ML14029A630 | Yes | Resolved - Closed |
| 532 | 6155 | 19-353 | Grady, Anne-Marie | 12/16/2011 | ML11350A074 | 7/30/2013 | ML13212A377 | Yes | Resolved - Closed |
| 532 | 6155 | 19-354 | Grady, Anne-Marie | 12/16/2011 | ML11350A074 | 7/30/2013 | ML13212A377 | Yes | Resolved - Closed |
| 532 | 6155 | 19-355 | Grady, Anne-Marie | 12/16/2011 | ML11350A074 | 7/30/2013 | ML13212A377 | Yes | Resolved - Closed |
| 563 | 6890 | 19-356 | Stubbs, Angelo | 11/30/2012 | ML12335A108 | 5/4/2013 | ML13128A023 | Yes | In Evaluation |
| 565 | 6933 | 19-357 | Vettori, Robert | 12/14/2012 | ML12349A373 | 4/26/2013 | ML13119A490 | Yes | Resolved - Closed |
| 565 | 6933 | 19-358 | Vettori, Robert | 12/14/2012 | ML12349A373 | 4/26/2013 | ML13119A490 | Yes | Resolved - Closed |
| 565 | 6933 | 19-359 | Vettori, Robert | 12/14/2012 | ML12349A373 | 4/26/2013 | ML13119A490 | Yes | Resolved - Closed |
| 565 | 6933 | 19-360 | Vettori, Robert | 12/14/2012 | ML12349A373 | 4/26/2013 | ML13119A490 | Yes | Resolved - Closed |
| 565 | 6933 | 19-361 | Vettori, Robert | 12/14/2012 | ML12349A373 | 4/26/2013 | ML13119A490 | Yes | Resolved - Closed |
| 565 | 6933 | 19-362 | Vettori, Robert | 12/14/2012 | ML12349A373 | 4/26/2013 | ML13119A490 | Yes | Resolved - Closed |
| 565 | 6933 | 19-363 | Vettori, Robert | 12/14/2012 | ML12349A373 | 4/26/2013 | ML13119A492 | Yes | Resolved - Closed |
| 572 | 6971 | 19-364 | Pohida, Marie | 3/12/2013 | ML13347B053 | 7/19/2013 | ML13202A004 | Yes | Confirmatory Action |

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| RAI Letter # | RAI ID | Question # | Technical Reviewer | RAI Issue Date | RAI Accession # | Response Date | Response Accession # | Open Item | Status |
|---|---|---|---|---|---|---|---|---|---|
| 572 | 6971 | 19-365 | Pohida, Marie | 3/12/2013 | ML13347B053 | | | Yes | Issued/Waiting for Response |
| 579 | 7048 | 19-366 | Pohida, Marie | 4/12/2013 | ML13102A114 | | | Yes | Issued/Waiting for Response |
| 579 | 7048 | 19-367 | Pohida, Marie | 4/12/2013 | ML13102A114 | | | Yes | Issued/Waiting for Response |
| 581 | 7063 | 19-368 | Phan, Hanh | 4/18/2013 | ML13347B227 | 7/24/2013 | ML13205A281 | Yes | Confirmatory Action |
| 581 | 7063 | 19-369 | Phan, Hanh | 4/18/2013 | ML13347B227 | | | Yes | In Evaluation |
| 591 | 7174 | 19-370 | Grady, Anne-Marie | 7/11/2013 | | 1/29/2014 | ML14029A625 | Yes | In Evaluation |
| 596 | 7199 | 19-371 | Thomas, George | 8/1/2013 | | | | Yes | Issued/Waiting for Response |
| 624 | 7280 | 19-372 | Pohida, Marie | 2/6/2014 | | | | Yes | Issued/Waiting for Response |