

Question #: CRU-1 SOP #1
 If AR has not been received, the CRU staff generates and sends traceable NOD within 10
 Question: business days after due date.

Scenario 2

EMC #	EntityDueDate	Completedate	Difference (Days)	Findings
15087	1/29/2010	2/26/2010	19	
14651	1/8/2010	4/8/2010	62	
14279	12/29/2009	3/12/2010	50	
14477	12/29/2009	11/6/2009	-36	
15465	12/29/2009	3/30/2010	62	
10690	4/15/2010	2/18/2010	-42	
14664	4/15/2010	2/16/2010	-44	
11284	4/15/2010	2/22/2010	-40	
11358	4/15/2010	2/19/2010	-41	
11472	4/15/2010	2/12/2010	-45	
14329	4/15/2010	3/9/2010	-29	
12540	4/15/2010	2/2/2010	-53	
12864	4/15/2010	1/4/2010	-73	
13474	4/15/2010	2/5/2010	-50	
AVG:			-19	

Question #: CRU1 SOP #2

Question: If AR is unacceptable, the CRU staff generates and sends traceable NOD within 10 business days of receipt.

<u>ECM#</u>	<u>Completedate (from Process Annual Report)</u>	<u>Completedate (from Prepare & Mail NOD)</u>	<u>Difference (Days)</u>	<u>Findings</u>
39652	2/12/2010	2/12/2010	0	
14461	8/28/2009	8/28/2009	0	
13469	6/1/2009	9/3/2009	68	
13577	8/12/2009	8/12/2009	0	
13583	10/8/2009	10/8/2009	0	
14488	2/11/2009	2/11/2009	0	
14489	11/4/2009	11/4/2009	0	
21475	11/23/2009	11/23/2009	0	
23843	9/21/2009	9/21/2009	0	
23881	12/18/2009	12/18/2009	0	
23889	11/2/2009	11/2/2009	0	
23920	11/20/2009	11/20/2009	0	
23960	9/25/2009	9/25/2009	0	
24016	2/26/2010	2/26/2010	0	
32077	12/22/2009	12/22/2009	0	
		AVG:	5	

Question #: CRU1 SOP CL #1

If registration changes occurred, did the CRU staff send request to the applicable RO to update information or initiate request for new or amended registration (RO-1)?

<u>ECM#</u>	<u>Yes/No</u>	<u>Findings</u>
18155	No	No corresponding entity in ECM
31454	Yes	
33303	Yes	
43578	No	No corresponding entity in ECM
22007	Yes	
23281	Yes	
22053	Yes	
33937	Yes	
21393	Yes	
42010	Yes	
42021	Yes	
41343	Yes	
25728	Yes	
33596	Yes	
25145	Yes	

Question #: CRU1 SOP CL #2

Question: If deficiencies are found, the CRU initiates Regulatory Activity to corresponding RO.

ECM#	Yes/No	Findings
40592	No	Could not find in CRU-1 main tab. Regulatory Activity was initiated but could not identify whether a deficiency was found.
39284	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
42129	No	This entity was in the main tab but the deficiency was a 0. Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
42315	No	This entity was in the main tab but the deficiency was a 0. Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
43026	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
43443	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
43526	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
43529	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
35149	No	This entity was in the main tab but the deficiency was a 0. Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit
40059	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
43543	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs.
43747	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
44171	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.
44331	No	This entity was in the main tab but the deficiency was a 0. Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit
44503	Yes	Found this entity in the CRU-1 main tab but the Controlnumbers do not match up between the two tabs. Once the Regulatory Activity is initiated, the control number changes which makes the audit trail difficult to follow.

Question #: CRU1 SOP CL #3

Question: For deficiencies, were the appropriate folders generated?

<u>ECM#</u>	<u>Yes/No</u>	<u>Findings</u>
9601	Yes	
10903	Yes	
10987	Yes	
9859	Yes	
10060	Yes	
10244	Yes	
10411	Yes	
11832	Yes	
11969	Yes	
11065	Yes	
11333	Yes	
11716	Yes	
13530	Yes	
21451	Yes	
13202	Yes	