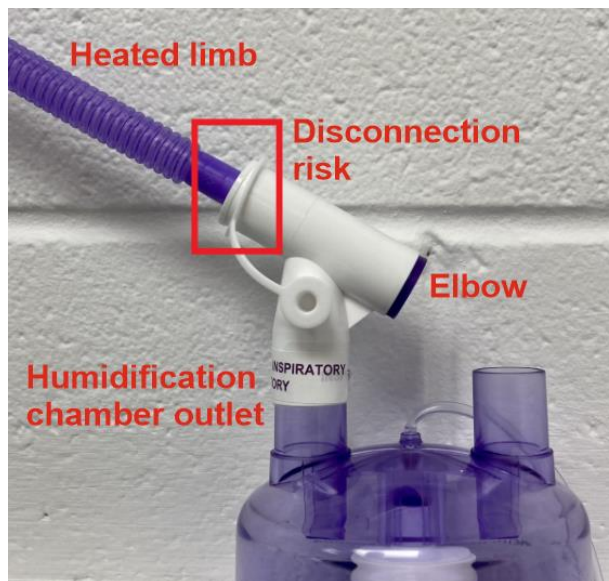


Urgent Field Safety Notice

Neonatal Breathing Circuits – risk of patient harm as a result of tubing (and a connector attached to the tubing) disconnecting from the elbow within Neonatal Breathing Circuits.

Please pass this Field Safety Notice (FSN) to all persons in your organisation who need to be aware of it.



- Type of Action:** To communicate an identified risk of patient harm as a result of tubing (and a connector attached to the tubing) disconnecting from the elbow within Neonatal Breathing Circuit.
- Devices:** Aquavent Neo Heated Ventilator Circuits, NeoFlow Humidified Oxygen Systems, Aquavent Neo nCPAP Systems
- Manufacturer:** Armstrong Medical Limited, Wattstown Business Park, Newbridge Road, Coleraine, BT52 1BS, Northern Ireland
- Date of Issue:** 03 Mar 2023
- For Attention of:** Healthcare professionals working in critical care areas of hospitals and all others to whom potentially affected devices have been transferred, including distributors.
- Scope of Action:** **Manufacturing LOT specific Field Safety Notice**
- Keywords:** Aquavent Neo Heated Ventilator Circuits, NeoFlow Humidified Oxygen Systems, Aquavent Neo nCPAP Systems, Neonatal Continuous Positive Airway Pressure, High Flow Oxygen Therapy

Summary

A report has been made to Armstrong Medical of tubing (and a connector attached to the tubing) disconnecting from the elbow within Neonatal Breathing Circuit contained within the below devices, as indicated in the image above. This could lead to (1.) delayed treatment to patient and/or (2.) oxygen desaturation, (3.) lung collapse (atelectasis), (4.) failure to maintain adequate pulmonary pressure support or (5.) failure to provide means of alveolar gas exchange, any of which could result in patient injury including cardiac arrest leading to irreparable impairment or fatality.

We are investigating a hospital report of a heated inspiratory limb disconnecting from an elbow connector attaching to the humidification chamber outlet. In this report, it has been possible for the tubing (and a connector attached to the tubing) to disconnect from the elbow during clinical use and with limited manipulation. This same construction feature is present on the expiratory limb of our neonatal dual heated ventilator circuits and is therefore included in this FSN.

All devices identified in Table 1 below should be taken out of clinical use and returned to Armstrong Medical.

Description of Action

All devices identified in Table 1 are to be returned to Armstrong Medical. Newly manufactured replacement product will be provided on request.

Action to be taken by Users

Users are requested to review the list of potentially affected devices in Table 1 and return the completed FSN response form to Armstrong Medical or to an appointed distributor. Until the investigation is complete, newly manufactured product will undergo disconnection testing as part of the production process. Where it is not practical to return devices, we request that you take the following immediate action with circuits in use:

1. Caregivers should increase the frequency of observation of the breathing circuit to check that the heated limb(s) has not become disconnected. During Nasal High Flow Oxygen Therapy (nHFOT) as potential disconnection may not result in an alarm, caregivers should be especially vigilant.
2. Caregivers should respond to any connected equipment alarms indicating (1.) loss of gas supply, (2.) loss of PAP (positive airway pressure) or (3.) low oxygen by checking that the heated limb(s) has not become disconnected.
3. If a heated limb has disconnected, or appears likely to disconnect with minimal manipulation, replace the breathing circuit or the heated limbs of the breathing circuit and continue clinical therapy. We request you to report any observed disconnections to Armstrong Medical.

Field Safety Corrective Action

This Field Safety Notice is published to facilitate a manufacturing LOT specific device field safety notice advising of product recall. See Table 1 for detail of all Product Codes and LOTs of finished medical devices that are subject to this field safety notice.

Table 1. Affected Devices

The six digits of the LOT number is the date of manufacture and follows the format – DDMMYY (meaning Day Day Month Month Year Year). For example: LOT number 010223 means that the devices were manufactured on 1st February 2023.

Product Codes Affected	Lot Number Affected			
AMCAI1303-004	110221			
AMCP1408-002	260718	281020	290321	040222
	250919	061120	190721	190522
	030120	071120	290721	100622
	010420	131120	300721	290622
	180920	251120	090921	070722
	121020	171220	081021	220722
	131020	181220	231121	211122
AMCP1408-003	100518	270120	181120	110222
	160419	120220	041220	070322
	090819	200420	010321	250722
	030919	190620	030621	020822
	100919	290620	020821	011122
	051119	030920	030821	
	021219	021120	160921	
AMCP1408-004	170918	210819	220120	
AMCP1408-005	250918	010420	070922	
	111218	160622	031122	
	180419	270722	131222	
	300919	310822		
	020320	060922		
AMCP1408-010	100418	170718	220319	
	240418	241018	080519	
	270418	261118	240619	
	060618	030119	180719	
	210618	060219	300919	
AMCP1409-013	160418	200819	040221	300621

	190618	220819	120321	250821	
	230818	010420	250521	041021	
AMCP1409-015	160919	190320	110520		
AMCP1409-017	080518	080119	140420		
	201118	240919	170620		
	271118	021019	080920		
	041218	071019	170920		
	111218	021219	120821		
	311218	170320			
AMCP1409-022	161118				
AMCP1409-023-1	120220				
AMCP1409-024	260219				
AMCP1409-028	180618				
AMCP1409-030	100418	310719	080920	120122	
	080518	091019	081220	090222	
	210618	161019	070121	150222	
	140818	191019	260121	230222	
	111218	181119	280121	050422	
	131218	201119	040521	010722	
	040119	231219	140621	050722	
	220119	290120	220621	220722	
	280219	030220	240621	240822	
	150319	050220	110821	070922	
	190319	140420	210921	210922	
	260319	150420	240921	041122	
	160419	200420	290921	190123	
	170419	100620	211021		
	130519	120620	021121		
	050619	150620	081221		
	170619	160620	151221		
	200619	240820	161221		
	160719	260820	221221		
	AMCP1409-031	060418	021019	010621	270522
150518		111019	170621	150622	
250518		011119	290621	220622	
100718		171219	170821	010722	
040918		230320	020921	080722	
161118		010420	150921	260722	
131218		260520	270921	120822	
070119		300520	201021	230822	
090119		170620	271021	200922	
100119		030820	281021	290922	
140119		111120	141221	201222	
220119		071220	050122	231222	
240219		111220	120122	230123	
260219		130121	270122		
280219		260121	040222		
010419		110221	020322		
010519		240221	160322		
160719	160421	290422			
AMCP1409-036	120418	120419	040320	021220	230222
	240518	300419	160320	081220	080322
	280818	060619	070420	240221	310522
	131118	020719	200420	220421	290622
	071218	280819	280520	290421	300622
	171218	111019	160620	080921	
	210119	041219	230720	011121	
	050219	091219	210920	181121	
AMCP1409-037	110518	020919	081220	091121	240822

	130618	270919	141220	101121	060922
	290618	171019	171220	111121	080922
	020818	221019	130121	151121	090922
	310818	241219	260121	191121	120922
	021118	251219	100221	131221	150922
	301118	160120	240221	171221	280922
	111218	230120	110321	211221	290922
	070119	280120	160321	310122	071022
	180119	290120	190321	150222	191022
	190119	020320	200321	210222	231222
	150219	030320	260321	150322	180123
	190319	100320	290321	160322	190123
	120419	110320	160421	280322	200123
	150419	120320	060521	290322	250123
	240419	130320	140521	310322	030223
	200519	140320	210521	050422	
	210519	080720	270521	210422	
	120619	240720	100621	130522	
	020719	250920	280721	090622	
	040719	280920	300721	220622	
	160719	191020	160821	240622	
	180719	201020	070921	270622	
	190719	181120	270921	060722	
	200819	191120	280921	100822	
	210819	251120	011121	120822	
	280819	261120	031121	170822	
	290819	271120	081121	230822	
AMCP1409-038	110119	230320	140722		
	190819	021020	011222		
	200220	140322	211222		
AMCP1409-039	170119	260219			
AMCP1409-042	080920	020222	271022		
	081020	040322	311022		
	220421	160322	171122		
	140521	130422	241122		
	300621	250522	071222		
	150721	010622	071222		
	240821	070622	081222		
	010921	040822	091222		
	211021	260822	131222		
	101121	010922	151222		
	121121	290922	211222		
	241121	131022	231222		
	031221	201022	160223		
AMCP1409-044	060618	030320	250521	100622	
	070618	040320	100621	130622	
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	281218	130320	130921	060722	
	180219	140320	240921	170822	
	220319	230720	261021	180822	
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	140619	290720	141221	090922	
	010819	300720	040122	150922	
	020819	130820	120122	160922	
	150819	220920	040222	171022	
	200819	230920	170222	091122	
	290819	280920	100322	040123	

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	300919	181120	210322	200123	
	301019	231120	230322	030223	
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	261119	261120	050422	405042	
	271119	271120	130522		
	171219	311220	160522		
	181219	210521	090622		
AMCP1409-045	090420	200420	121020		
	200420	020620	171220		
AMCP1409-049	180418	170119	270120	160821	150622
	300418	220119	060220	240821	300622
	010518	120219	240220	250821	250722
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	240518	080319	040320	061021	210922
	310518	010419	170320	071021	220922
	060618	030419	230320	081021	251022
	180618	240419	060420	091021	091122
	290618	140519	090420	101021	211122
	170718	210519	240420	111021	221122
	020818	290519	110520	181121	231122
	130818	030619	270520	221121	241122
	280818	100619	020620	210122	180123
	290818	270619	030620	310122	200123
	040918	110719	040620	220222	210123
	021018	300719	290620	230222	030223
	041018	130819	100720	090322	
	311018	140819	210920	300322	
	021118	280819	290920	310322	
	061118	090919	221020	010422	
	271118	180919	271020	020422	
	301118	230919	041120	220422	
	041218	141019	091220	230422	
	061218	231019	130421	090522	
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	080119	091219	030621	110522	
	150119	231219	070721	140622	
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AMCP1409-055	060718	240220	270521	160922	
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	311019	160421	160622		
AMCP1409-057	250219	170320	030920		
	231219	240320	231221		
	140120	020620	241221		
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	050319	041220	150622		
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	310518	230719	140920	130422	
	020718	300719	221020	240522	
	060718	230919	121120	140722	

	080818	101019	311220	180722	
	290818	061119	100221	200722	
	240918	111119	240221	171122	
	151018	041219	130421	231222	
	061118	200120	230621	040123	
	221118	050220	270721	190123	
	030119	090320	070921		
	040219	140520	031121		
AMCP1409-066	020518	270918	120220	261020	
AMCP1409-068	190618	280819	171120	210122	
	240818	230919	080321	220322	
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	221018	220120	300621	150422	
	201118	230320	060721	090522	
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	010419	030920	080921	131222	
	240419	221020	300921	100123	
	270619	271020	011121	080223	
	250719	041120	171221	100223	
AMCP1409-071	131218	240220	071021	110822	
	240219	020320	051121	241022	
	260219	230320	171221	251122	
	120319	061120	110122	240123	
	051119	301120	160522		
	101219	141220	080822		
AMCP1409-072	030220	181120	121121	250722	
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	060420	260421	210122	210922	
	260820	230621	070222	191022	
	150920	300921	100522	281022	
	301020	081121	260522	141122	
AMCP1409-073	311218	260219	160719	121120	
AMCP1409-074	150618	180320	071221		
	170619	130521	060722		
AMCP1409-077	250418	260918	290321	270422	
	070918	221018	230322		
AMCP1409-079	280918	200420	250521	180822	
	140119	020620	020721	031122	
	100619	290720	261121		
	180719	221020	240122		
	270120	220321	010422		
AMCP1409-080	260418	030619	280520	090321	
	220518	170719	290720	190321	
	150618	300819	130820	291021	
	020818	090919	230920	261121	
	280818	111119	231020	270722	
	231018	261119	091120	150922	
	151118	030220	191120	210922	
	301118	170320	031220	261022	
	040319	240320	070121	241122	
	080419	070520	170221	301122	
AMCP1409-088	040718	221118			
AMCP1409-090	020818	090519	160120	030920	150922
	191018	100519	200120	100920	031122
	231018	140519	050220	110920	010223
	291018	230519	120220	220321	
	201118	050619	190320	210921	

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	280119	200819	070520	050422	
	090419	090919	020620	270522	
	100419	051219	040620	240622	
	240419	171219	080720	250822	
AMCP1409-094	101219	270422			
AMHO1509-009	240418	030619	200120	291020	200722
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	160518	240619	280120	131120	080822
	290518	090719	180220	021220	110822
	191118	180719	200220	031220	250822
	041218	220719	260220	041220	050922
	191218	240719	020320	051220	060922
	201218	010819	160320	280121	070922
	170119	210819	230320	090221	160922
	060219	030919	250320	100221	280922
	070219	120919	060420	140421	300922
	120219	190919	080420	190521	011022
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	090519	251119	011020	100122	260123
	210519	060120	201020	110122	
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	140818	060319	141021	010822	
	231118	010819	181021	241022	
	030119	290120	141221	310123	
	110219	060420	220222		
	220219	181120	250322		
AMHO1509-011	250418	030619	130520	010721	120123
	100518	170919	051020	240122	
	201218	240919	141020	010422	
	290419	060220	290321	041122	
AMHO1509-014	060418	120319	140622	200223	
	250518	301019	021122		
	120618	161020	031122		
	260618	181120	050123		
	191018	080721	030223		
AMHO1509-015	060819	141020			
	020320	210722			
	240320				
AMHO1509-018	210518	230919	030920	141221	
	190918	231219	170521	020822	
AMHO1509-019	210518	030920	270422		
	190918	170521	280422		
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	231219	231221	090822		
	170320	241221			
AMHO1509-045	291118	261119	200522	241122	
AMHO1509-048	260918	311019	030120	131120	111022
AMHO1509-050	060319	190620	290321	220822	
	260419	301120	230621	061022	
	020919	091220	100122		
AMHO1509-051	100519	181119	251119	301120	290321

AMHO1509-052	080819	030720	230721	080222	121022
	011119	280820	240721	220222	151122
	220120	250920	090821	030322	281122
	040220	171120	310821	270422	301122
	260220	031220	010921	040522	121222
	050320	270121	070921	100522	191222
	180320	080221	300921	090622	100123
	210320	180321	201021	160622	170123
	030420	040521	101121	190722	240123
	130520	110521	171121	260722	310123
	020620	120521	151221	010922	210223
	030620	310521	040122	290922	
AMHO1509-053	160120	210320	240420	121222	
AMHO1509-055	050721	191121	180222	030123	200223
	080921	141221	200422	050123	
	170921	210122	031122	310123	
AMVC1774-152	260919				
AMVC1774-160	100518	030919	290720	181021	261022
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	070818	270120	160321	250222	
	151018	120320	130421	180722	
	160419	170320	030621	270722	
	170619	040420	280721	020822	
AMVC1774-161	150618	040820	051020	271020	
AMVC1774-162	260418	190718	180419	230620	220222
	110618	130818	180619	040820	270422
	150618	101018	300719	080221	240622
	290618	301018	280819	300621	250622
	030718	311018	181019	160921	270922
	100718	130319	140420	081121	
	160718	170419	220620	091121	
AMVC1774-163	010518	240719	230320	041220	280222
	100818	040919	010420	210121	220622
	301018	111119	190620	060721	211022
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	100619	060220	141020	210122	291122
	230719	240220	121120	220222	
AMVC1774-164	300418	110618	010422		
AMVC1774-165	310518	240719	040820	141221	111022
	091018	151019	121121	110122	
	270219	190620	091221	220622	
AMVC1774-167	020718	300419	221019	210320	051222
AMVC1774-171	060319	290720	140621		
	030619	010221	170621		
AMVC1774-172	030119				
AMVC1774-173	240418	021018	200420	100621	
	040518	160419	041120	070122	
	080518	090819	101120		
AMVC1774-177	250418	030619	090420	290321	091122
	270618	060619	141020	300621	291122
	151018	150819	101220	011021	
	081118	230919	171220	240122	
	010519	040220	181220	290622	
AMVC1774-178	170918	300919	111220	200521	270922
	180419	220120	231220	230822	
AMVC1774-179	200718	110918	110419	240619	201020
AMVC1774-181	010420				
AMVC1774-183	140119	141221	070422		

AMVC1774-184	170320				
AMVC1774-185	201021	050522	250722		
AMVC1774-186	141020	100122			
AMVC1775-150	250518	150618	170918	040319	
AMVC1775-157	180418	290319	010420	210621	270422
	060718	210619	170520	210721	020622
	300119	090719	090620	030921	150822
	120219	180719	150920	131021	
	060319	171019	170621	140322	
AMVC1775-160	090719	031019	121020	171220	240122
AMVC1775-162	230418	260919	250121	260521	031122
	110518	251119	300321	011121	
	090519	110920	120421	120422	
	240719	170920	250521	050522	
AMVC1775-163	180518	150519	250320	011020	160123
	110618	250519	010420	161020	
	140618	240719	110520	231120	
	150618	231019	190620	041220	
	120219	200120	220620	041021	
AMVC1775-164	030518	160419	151119	170221	070422
	110618	240419	051219	040521	010822
	150618	300419	060220	140721	120922
	290618	300519	030320	220721	270922
	180718	210619	230320	271021	081222
	161118	240719	010520	011121	030223
	261118	060819	040920	081121	
	301118	280819	150920	270122	
	290119	180919	160920	210222	
	060219	281019	271020	010422	
AMVC1775-165	060219	271120			
AMVC1775-167	310818	270619	090420	020821	
	061218	301219	300621		
AMVC1775-168	110618	311019	290720	051121	
	060319	171219	280920	170222	
	280819	070120	040121	230123	
	300919	010420	200421		
	171019	120620	170821		
AMVC1775-170	201020				
AMVC1775-171	031219	240920	251021	240622	231122
	020320	270121	141221	290622	
	010420	180321	070222	151122	
AMVC1775-174	180718	240119	250719		
AMVC1775-177	060120	150622			
AMVC1775-178	160418	260319	010420	140421	
	270918	030619	190620	270921	
	150119	160120	131020	190722	
AMVC1775-181	170918	180419	270422		
AMVC1775-182	110419	240619	150920		
AMVC1775-184	260418				
AMVC1775-185	220319	040919	230320		
AMVC1775-187	041018				
AMVC1775-189	160418	170619	100220	240222	
	061118	060919	040820	270422	
	110119	071019	110321	150622	
	030619	200120	060821	161122	
AMVC1775-190	060418	150519	230320	271020	210722
	170418	060819	070420	110821	220722
	230418	280819	040820	021121	

	030718	060919	250820	141221	
	271218	180919	040920	010422	
AMVC1775-191	100518	301118	070422		
AMVC1775-192	010518	260219	301219	041220	
	220518	220319	230320		
	250518	100619	290720		
	211218	051219	210920		
AMVC1775-194	110418				
AMVC1775-195	070818	311218	050619	160719	290321
AMVC1775-196	190119	240220	160421	091221	210722
	110219	170320	190421	101221	270722
	180219	190620	280421	141221	010822
	240219	040820	180521	040122	100822
	260219	210920	240521	250122	220922
	220319	111120	250521	310122	230922
	230419	191120	270521	220222	051022
	240419	241120	240621	100322	191222
	010819	260121	060821	120422	120123
	210819	150221	080921	110522	090223
	020919	220221	081121	160622	
	021219	090321	171121	010722	
AMVC1775-198	040219				
AMVC1775-199	240219	260219			
AMVC1775-200	060919	010420	090420		
AMVC1775-201	050419	290120	270422	310522	
	030619	141221	060522	010722	
AMVC1775-203	210519	170919	010221	261021	011022
	140619	230919	110221	041121	031122
	240619	031019	150221	100122	131222
	030719	311019	020621	110122	
	220719	081220	090621	270522	
	020819	141220	290921	020822	
	190819	210121	131021	300922	
AMVC1775-204	090120	161220	230621	010222	210922
	200120	311220	290621	140222	220922
	020320	080121	080721	010322	280922
	300520	130121	230821	250322	041022
	150620	150121	020921	300322	071022
	060720	260121	201021	010422	191022
	070720	040221	041121	140422	011122
	250820	180221	081121	270422	151122
	020920	220221	181121	130522	121222
	231020	260221	251121	200522	131222
	261020	150321	261121	260522	141222
	301020	230321	081221	190722	201222
	111120	130521	161221	080822	010223
	271120	250521	211221	050922	030223
	021220	010621	100122	150922	100223
	091220	110621	130122	160922	210223
AMVC1775-206	280320	080621	060922		
	060121	240921	031122		
AMVC1775-207	280320	221221	011222		
	021020	060722	061222		
AMVC1775-208	030921	201021			
AMVC1775-209	150223				

Armstrong Medical Limited confirms that this Field Safety Notice has been notified to the UK Competent Authority - Medicines and Healthcare Products Regulatory Agency (MHRA).

Armstrong Medical Limited confirms that this Field Safety Notice has been notified to all Competent Authorities, in jurisdictions where the device is made available on the market including, but not limited to Ireland, Australia, Canada, Japan and USA.



Field Safety Notice Response Form

FSN Reference: SI22-170 Date: 03 Mar 2023

Hospital or Delivery Location Name: _____

Hospital or Delivery Location Address: _____

Please complete the information below and return to quality@armstrongmedical.net. Alternatively, please telephone Armstrong Medical on 00 44 (0)28 70356029 and ask for the Sales Department.

- We confirm that we have received this FSN and have distributed it to relevant individuals or departments within our organisation.

Please also tick one of the following options:

- We do not have remaining stock of the affected products.
- We have stock of affected products and confirm that we wish to retain the devices until replacements can be provided and are committed to following the advice for continued safe use of these devices as detailed in the FSN. Quantity of replacements required _____.
- We have stock of affected products and confirm they have been quarantined for return to Armstrong. Quantity of stock returned _____. Quantity of replacements required _____.
- Armstrong Medical Distributors Only:** We confirm that we have received this FSN and have distributed it to all customers that have been supplied with the products listed in Table 1.

Form Completed by:

Name: _____

Department or Position: _____

E-mail Address: _____

Date: _____