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Air Quality Improvement Investigation Report

9th May 2018

Royal Surrey County Hospital

Introduction:

Routine processing of tissues for histopathological analysis involves the use of various harmful chemicals. Whilst it necessary to use these chemicals to achieve the desired results, it is of paramount importance to maintain a safe working environment for employees.

Formaldehyde is employed in Histology departments as a fixative, usually diluted to a 10% solution of formalin or as is used at the Royal Surrey County Hospital (RSCH), formal saline.

Formaldehyde is classed as harmful, a respiratory irritant, toxic if ingested and a suspected carcinogen [1]. Even when used at a concentration of 10% as formal saline, it has a strong vapour which can cause irritation of the eyes, mouth, skin, mucous membranes and upper respiratory tract. Some staff are naturally more sensitive to formalin saline, and others can develop sensitivities due to prolonged contact.

Despite having control measures in place, multiple non-conformities have been raised over the last couple of years regarding breaches of workplace exposure limits for formaldehyde. This report discusses the nature of these non-conformities, actions taken to mitigate the risks and a recent trial of new technology designed to reduce chemical vapours in the workplace.

Use of formaldehyde in the RSCH Histopathology Department:

To date, derivatives of formaldehyde such as formal saline are among the most commonly used Histology fixatives in the UK if not across the world. At the RSCH, t issue specimens are immersed in formalin saline to a ratio of approximately 1:10 and allowed to 'fix' for varying amounts of time depending on the size and density of the tissue. Fixation is a chemical reaction during which the tissue is preserved in as close to a life-like state as possible, enabling pathologists to ascertain any inherent disease processes. Fixation arrests the processes of autolysis and putrefaction and also gives rigidity to the tissue, helping it to withstand subsequent histological processes [2].

The Histopathology department tends to use 60ml pots of formal saline for biopsy specimens, but to achieve a ratio of 1:10 it can be appreciated that for larger surgical specimens a significant amount of formal saline needs to be used, ie sometimes 5 and 10 litre containers. The department processes around 74,000 cases per annum, and uses around 400 litres of formal saline per month.

Management of formaldehyde exposure:

Current control measures include use of AFOS downdraft tables in the specimen dissection area, personal protective equipment (laboratory coats, gloves, goggles, plastic aprons, sleeve protectors, disposable face masks) and good laboratory practice when lifting specimen pots, securing lids etc.

Downdraft tables work by extracting air away from the surface of the table in a downwards direction, therefore reducing formaldehyde vapours emanating from specimens being examined [3]. They are subject to regular maintenance and are checked for airflow efficiency at regular intervals by the cut-up lead. However they are not installed in every area of the department where formal saline is used.

Monitoring of Air Quality:

Air quality is continually monitored as part of on-going health and safety measures employed within the department. Each of the 3 Surrey sites within the BSPS network has a HtV-M formaldemeter. This is a monitoring device that measures the amount of formaldehyde vapour in the surrounding environment, either at regular intervals (1 min, 5 mins, 10 mins etc) or on an ad-hoc basis [4]. Each site has a yearly monitoring schedule which involves the formaldemeter being placed at key areas of formal saline usage for one week at a time. This data is downloaded each week and analysed to see if there have been any breaches of the workplace exposure limit (WEL) of 2ppm that have exceeded 15 minutes [5]. In addition to this, the department also uses Leica Airchek badges to monitor air quality. These are used as per schedules specific to each site, and can be worn for a period of 8 hours (time-weighted analysis (TWA) or 15 minutes (short-term exposure limit (STEL) [6].

The WEL for formaldehyde is 2ppm regardless of whether a TWA or STEL analysis. Badges are sent away for analysis and reports scrutinised by laboratory management for any breaches.

Any breaches of the WEL are raised as departmental non-conformities and discussed in the weekly 'Root Cause Analysis' group to help establish causes and effective solutions.

Multiple non-conformities have been raised regarding air quality over the last few years within the department. A trend analysis of such non-conformities relating to health and safety was performed in March 2018, spanning the period from 23/12/2016 to 05/03/2018.

A total of 30 non-conformities were raised across all 3 sites with the following distribution:

SITE:	RSCH	FPH	SPH
NUMBER OF N.C's	27	1	2

Included within these 30 non-conformities raised were 5 instances of WEL breach picked up in the weekly formaldemeter downloads (*prior to 25/01/2018) and 14 instances of breach picked up by the Airchek badges. Actions to date had included huddle announcements to staff reminding of best practice, keeping lids on specimen pots, washing down AFOS tables to reduce residual pools of formal saline, even competence re-assessment, but spikes in the level of formaldehyde vapour continued to be recorded. Discussions among the Root Cause Analysis group concluded that actions to date were proving ineffective.

The graph below summarises formaldemeter recordings for the week of 19/12/17 – 07/01/18 whilst the located in the cut-up room adjacent to an AFOS table. Activities performed in this area will have included specimen dissection and changing of processing solutions.

This data is displayed upon the departmental health and safety notice board.

The graph shows multiple episodes where the levels of formaldehyde vapour have exceeded the WEL of 2ppm.

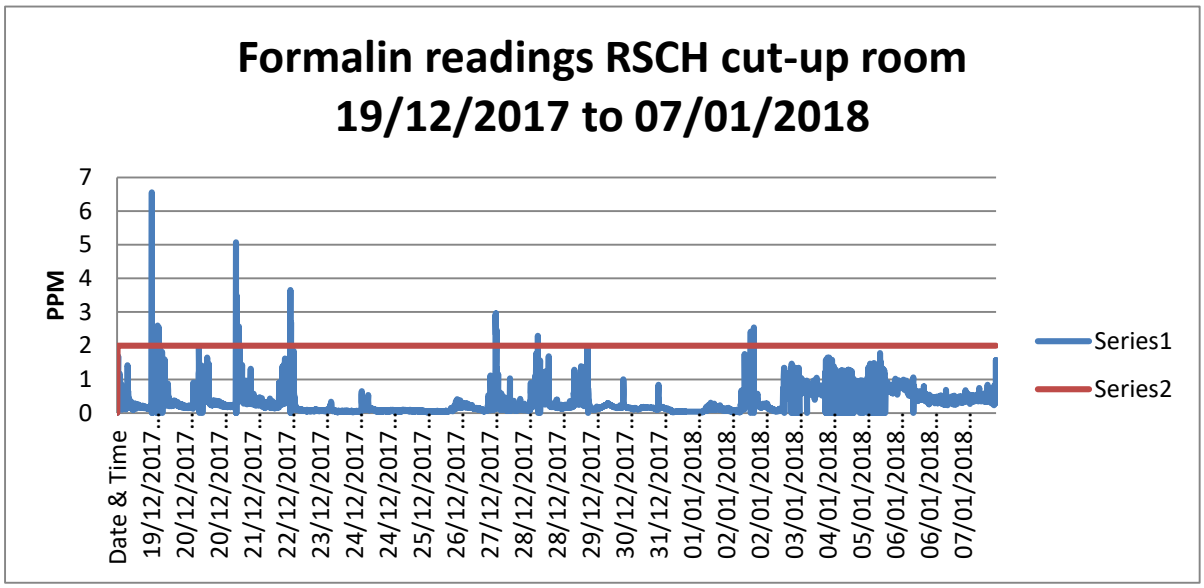


Table 1 shows the data from the breaches specifically and which lasted over 15 minutes:

Table 1: Example of WEL breaches recorded by the HtV-M formaldemeter in the RSCH cut-up room (AFOS bench 1)

Date:	Time of breach:	PPM:	Time of next reading:	PPM:	Time at which PPM <2	PPM:	Total time (mins)
19/12/17	09.05	6.552	09.26	0.671			21
	09.33	2.537	09.46	0.564			13
	12.16	2.046	12.25	2.601	12.40	1.016	24
	12.45	2.043	12.53	1.438			8
	13.10	2.541	13.20	0.823			10
21/12/17	9.00	5.068	09.13	1.322			13
	9.20	2.235	9.26	0.856			6
	09.30	3.496	09.38	1.324			8
12/01/18	09.00	2.334	09.05	0.343			5

The graph below summarises the formaldemeter readings from 15/01/18 – 21/01/18 when the formaldemeter was placed into the tissue processing room. There is no AFOS downdraft extraction in this area. As can be seen there are multiple breaches, several of which are over 3 times the WEL.

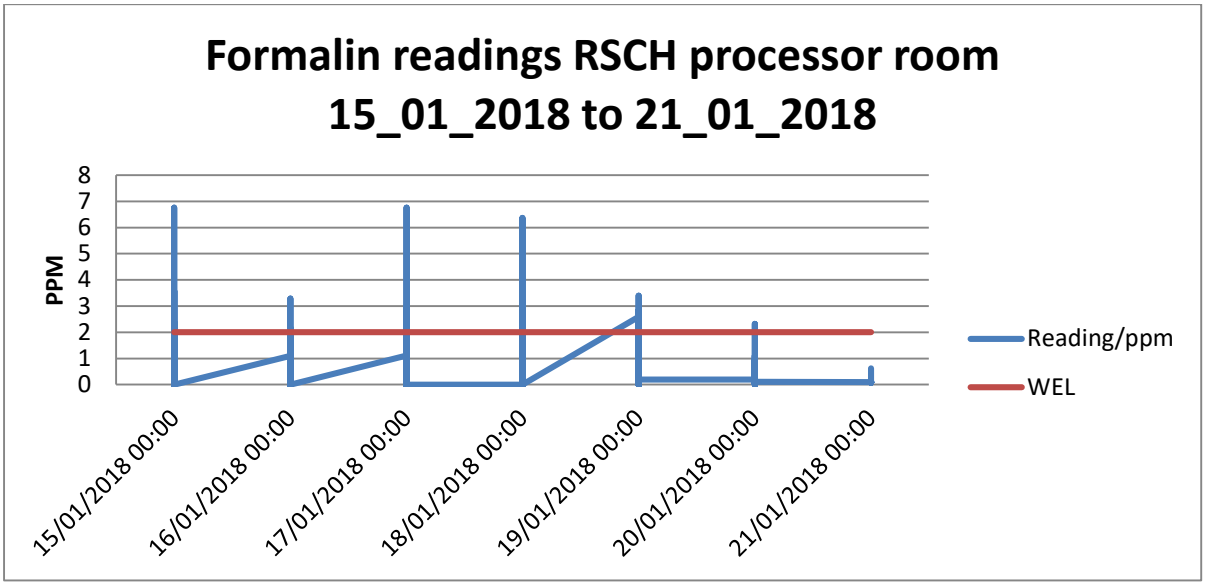


Table 2 shows the data from the breaches specifically and which lasted over 15 minutes:

Table 2: Example of WEL breaches recorded by the HtV-M formaldemeter in the RSCH tissue processor room

Date:	Time of breach:	PPM:	Time of next reading:	PPM:	Time at which PPM <2	PPM:	Total time (mins)
15/01/18	13.08	6.758	13.41	0.778			33
	16.03	3.579	16.20	0.566			17
	21.20	2.383	21.36	1.06			16
16/01/18	08.30	3.288	08.45	0.417			15
	23.15	2.16	23.33	1.909			18
17/01/18	09.21	2.207	09.40	1.163			19
	18.00	6.765	18.45	0.719			45
	20.18	2.295	20.38	1.112			20
	21.08	2.353	21.28	1.02			20
	21.58	2.997	22.20	1.298			22
	23.31	2.258	23.51	1.345			20
18/01/18	00.08	2.363	00.30	1.369			22
	05.18	2.547	05.36	1.27			18
	12.56	2.258	13.18	1.287			22
	13.31	2.083	13.46	0.861			15
	14.51	3.192	15.10	1.661			19
	17.26	6.364	17.56	1.155			30
	19.23	2.35	19.41	1.834			18
	21.01	2.533	21.21	2.521	21.43	1.778	42
	22.16	2.163	22.35	1.131			19
	22.50	2.143	23.10	1.251			20
19/01/18	00.00	2.587	00.21	1.501			21

	09.40	2.132	09.58	1.403			18
	13.10	3.395	13.26	0.542			16
	15.40	2.832	15.58	0.809			18
20/01/18	12.50	2.317	13.01	0.823			11

As table 2 shows, of 26 episodes of formaldehyde levels exceeding 2ppm, 23 appear to have lasted longer than 15 minutes = 88%

The processor room has 3 doors (one of which is a fire escape) but no actual windows *per se*, instead it has glass in the partition walls. There is no AFOS benching in the room. The temperature is usually a few degrees higher than other areas of the laboratory due to the heat output of the processors, and staff have fed back that it can be an unpleasant environment to work in at times.

The processors each have carbon filters to absorb some fumes and these are changed as per manufacturer's instructions, but as demonstrated by the formaldemeter readings, there are still instances of high levels of formaldehyde vapour.

It has been extremely difficult to implement effective CAPA in this area as it is not possible to put windows in or downdraft systems.

Technology trial:

In November 2017, a local company, Surrey Diagnostics Ltd made contact with the department and asked to come in and talk about some new air purification technology being implemented in healthcare environments. During a meeting on 21/11/2017 two representatives from the company gave an overview of the 'Biokker system, which utilizes photo-catalytic oxidation technology to remove chemical impurities and pathogens from the air [7].

The representatives were given a tour of the department and felt that installation of a Biokker unit could be of benefit in areas of the laboratory where formaldehyde was being used.

It was agreed that a unit would be installed in the processing room as this is an area where multiple breaches had been recorded previously. There are 6 tissue processing machine, all containing large quantities of formal saline, xylene and Industrial Methylated Spirit (IMS). As mentioned, there is no downdraft benching or fume extraction in this area other than the carbon filters within each processor , and downloaded data has shown significantly high levels of formaldehyde.

Other applications such as extraction of xylene and alcohol fumes were also discussed. It is known that the formaldemeter can be affected by high levels of these chemicals as well, and xylene levels are also monitored within the department using Airchek badges. It was felt that the Biokker unit could be of benefit in reducing these vapours also.

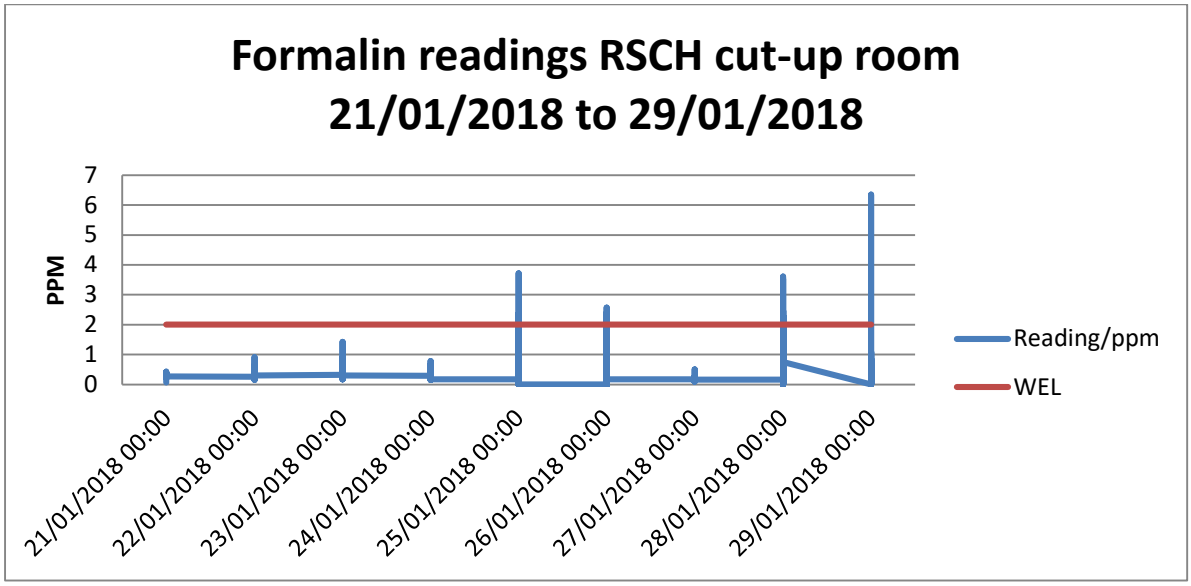
Method:

The Biokker unit was installed in the processor room on 25/01/2018 and left to run alongside the formaldemeter until 23/04/2018. During this time the formaldemeter was downloaded each week and the data analysed. The unit required minimal set-up, and has not required any intervention /

maintenance since installation by RSCH staff. The green light located on the front panel indicates functionality, as mentioned there has been no other requirement to operate the unit.

Results:

The graphs below show the first readings after the Biokker unit was installed on 25/01/2018. As can be seen, there are still episodes of formaldehyde levels exceeding 2ppm, although in the 2nd week the breaches are less frequent.



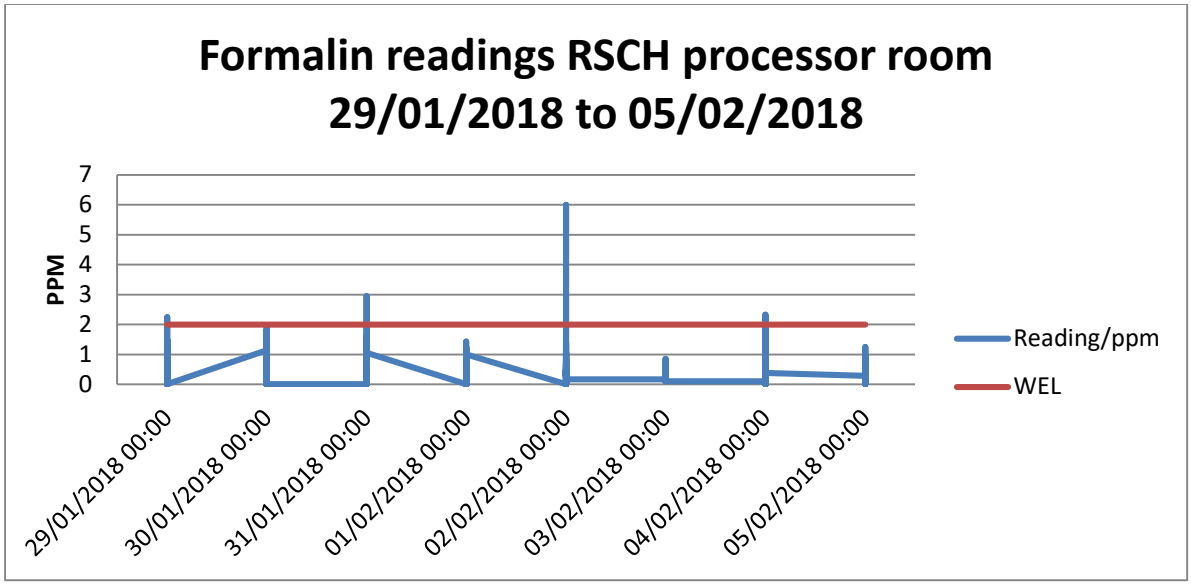


Table 3 shows the data from the breaches specifically and which lasted over 15 minutes:

Table 3: WEL breaches recorded by the HtV-M formaldemeter in the RSCH tissue processor room from 25/01/18 to 05/02/18

Date:	Time of breach:	PPM:	Time of next reading:	PPM:	Time at which PPM <2	PPM:	Total time (mins)
25/01/18	12.31	3.717	12.50	0.965			19
	20.55	2.38	21.13	1.206			18
	22.33	2.214	22.41	1.112			8
	23.11	2.088	23.30	1.802			19
26/01/18	01.05	2.577	01.25	1.231			20
	12.13	2.24	12.26	0.692			13
	13.20	2.405	13.36	1.40			16
28/01/18	11.43	2.169	11.56	1.567			13
	12.08	2.475	12.23	2.312	12.38	1.76	30
	13.53	2.462	14.11	1.778			18
	15.20	3.612	15.45	2.031	16.05	1.98	45
	16.25	3.537	16.51	2.351	17.15	1.849	50
	17.35	2.214	17.55	1.699			20
29/01/18	10.16	6.349	10.41	0.412			25
	17.05	2.241	17.16	0.731			11
31/01/18	11.05	2.952	11.21	0.575			16
02/02/18	09.10	5.998	09.31	0.197			21
04/02/18	12.41	2.322	12.58	0.78			17
	13.06	2.15	13.26	1.343			20

On 05/02/18 the formaldemeter was re-calibrated to 28°c to reflect the temperature in the processor room.

The graph below shows a summary of the readings from 05/02/18 to 13/02/18. Breaches continued to be seen, but as shown in table 4, these were becoming less frequent, generally lower ppm readings and more were resolving in under 15 minutes.

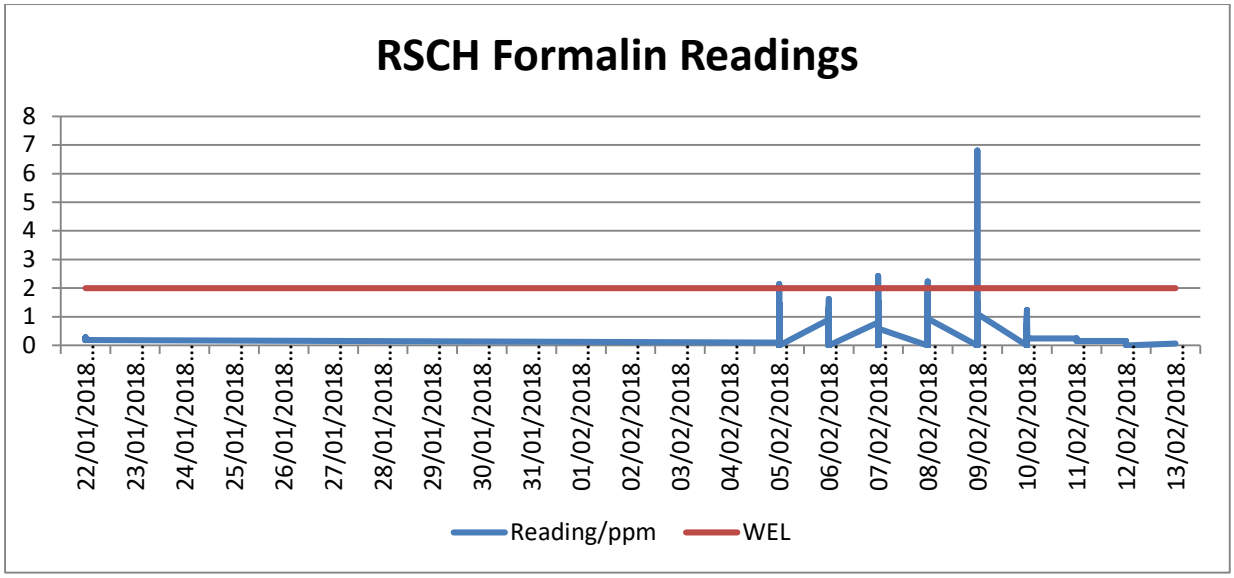


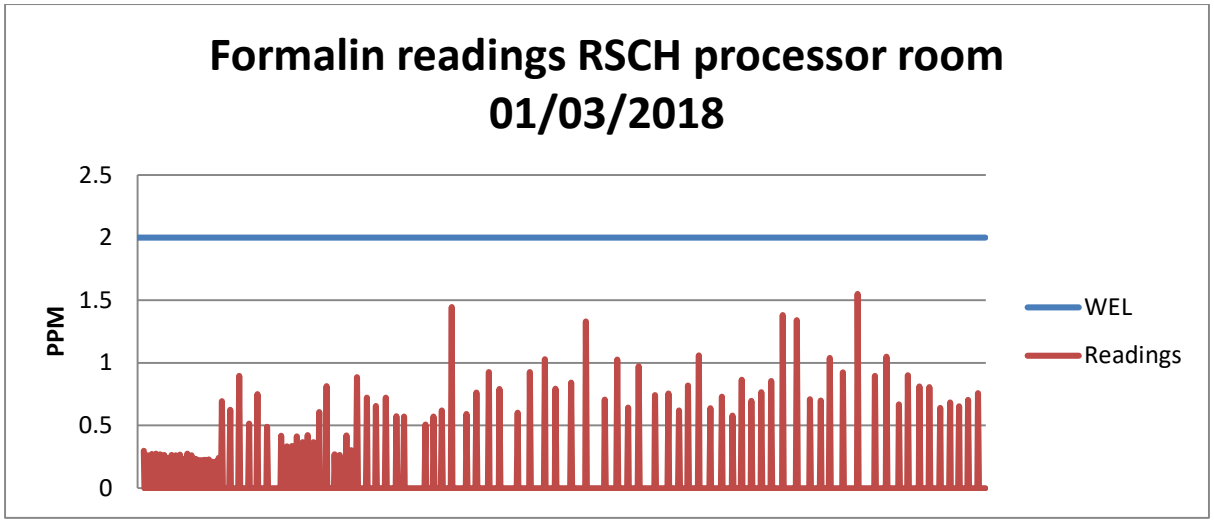
Table 4 shows the data from the breaches specifically and which lasted over 15 minutes:

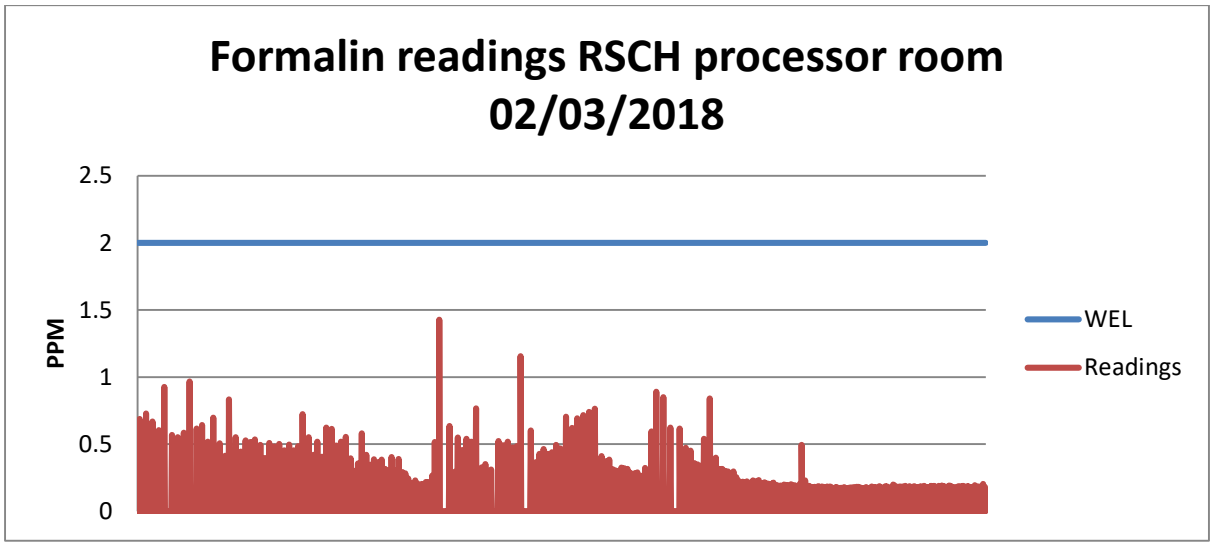
Table 4: WEL breaches recorded by the HtV-M formaldemeter in the RSCH tissue processor room from 05/02/18 to 26/02/18

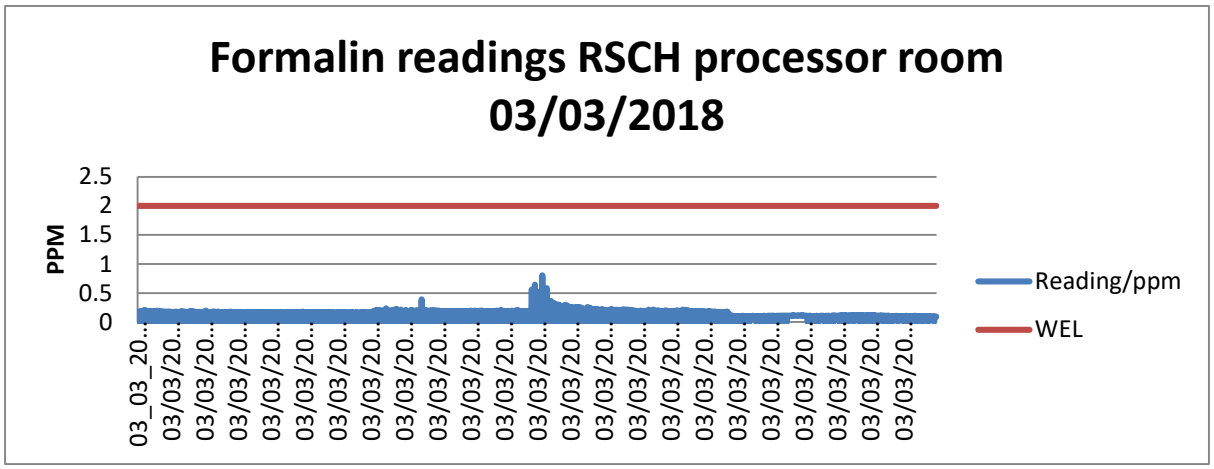
Date:	Time of breach:	PPM:	Time of next reading:	PPM:	Time at which PPM <2	PPM:	Total time (mins)
05/02/18	16.41	2.14	16.56	0.9			15
07/02/18	09.31	2.422	09.45	0.376			14
08/02/18	09.11	2.23	09.25	0.68			14
09/02/18	13.50	6.8	14.23	0.18			33
26/02/18	12.48	3.333	13.28	1.365			40

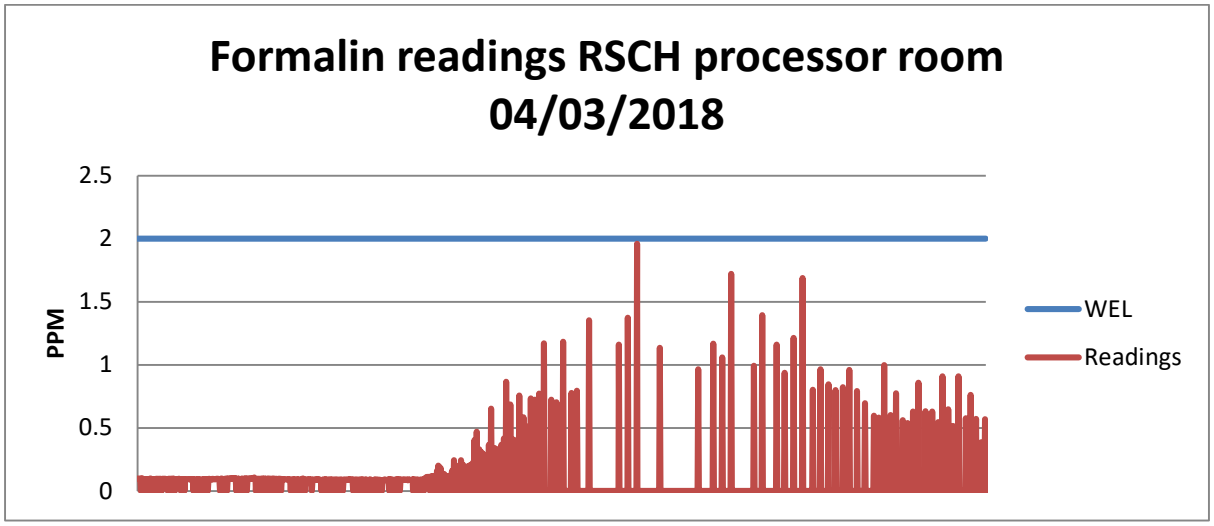
A summary of the initial data was fed back to Surrey Diagnostics, who felt that the Biokker unit would show improved function if it were rotate so that it was taking in air from the right side rather than the left, as this was more in the direction of the processing machines. On 28/02/2018 the unit was rotated.

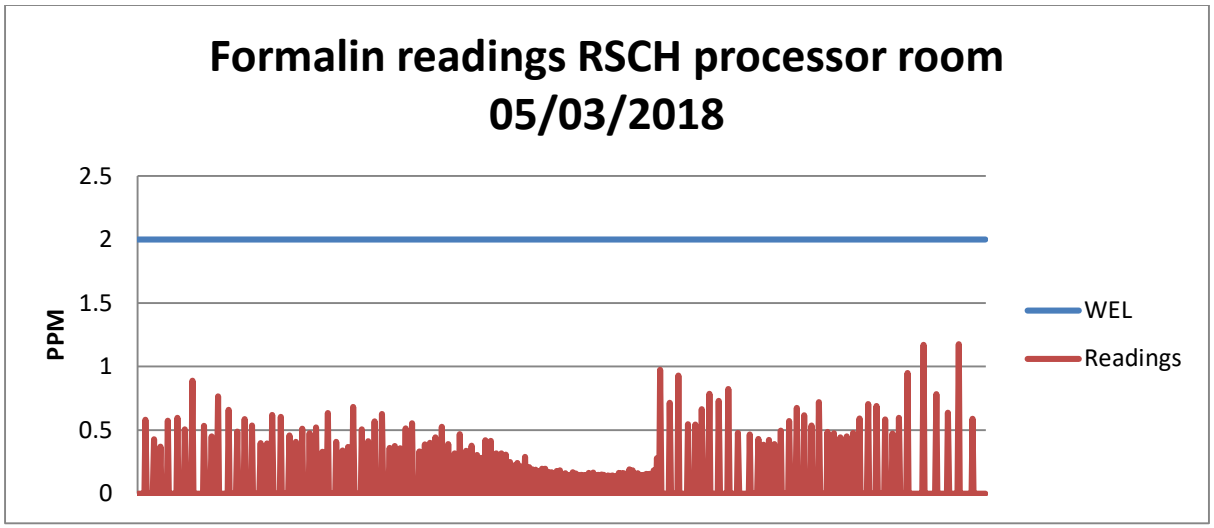
The graphs below show daily summaries of formaldehyde levels in the RSCH processor room from 01/03/2018 to 23/04/2018. The recording frequency of the formaldemeter was changed from 5 minute to 1 minute intervals.

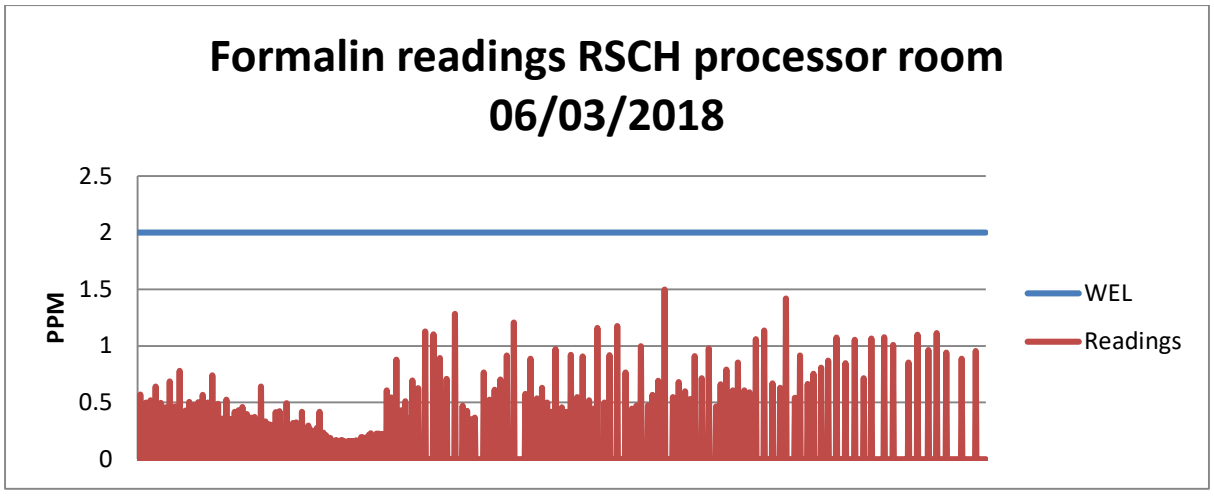

Formalin readings RSCH processor room 01/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

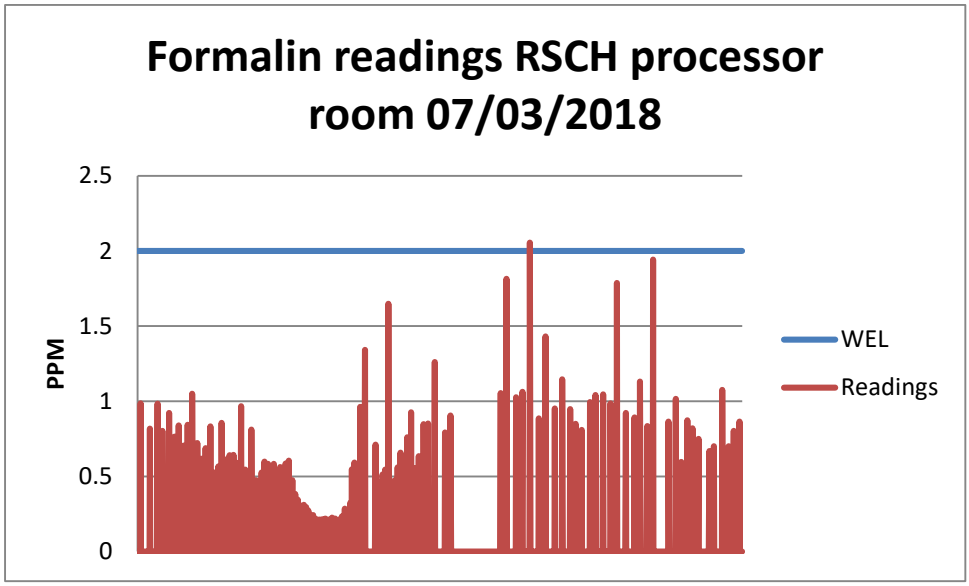

Formalin readings RSCH processor room 02/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

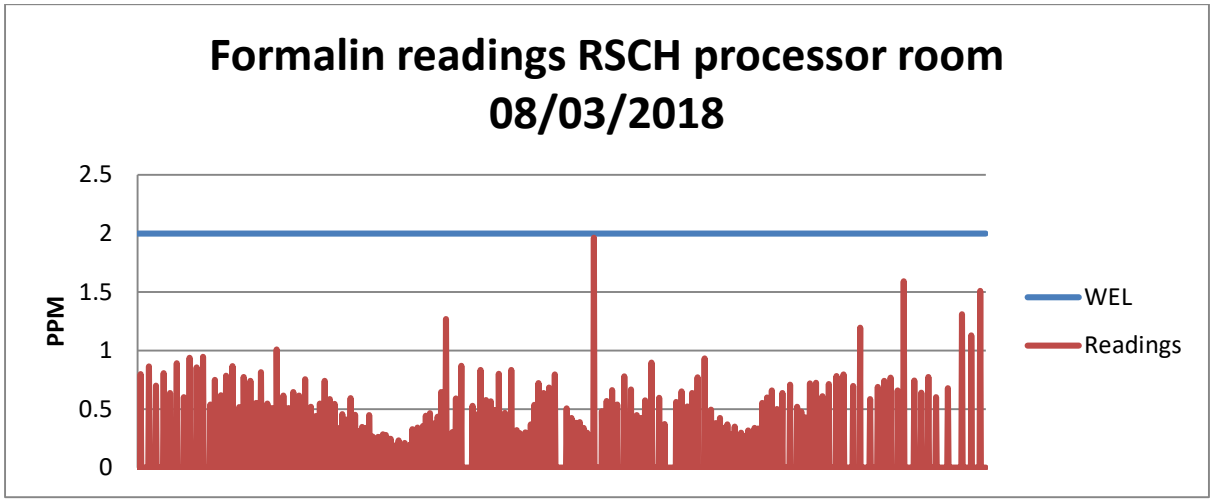

Formalin readings RSCH processor room 03/03/2018
PPM
2.5
2
1.5
1
0.5
0
03_03_20...
03/03/20...
Reading/ppm
WEL

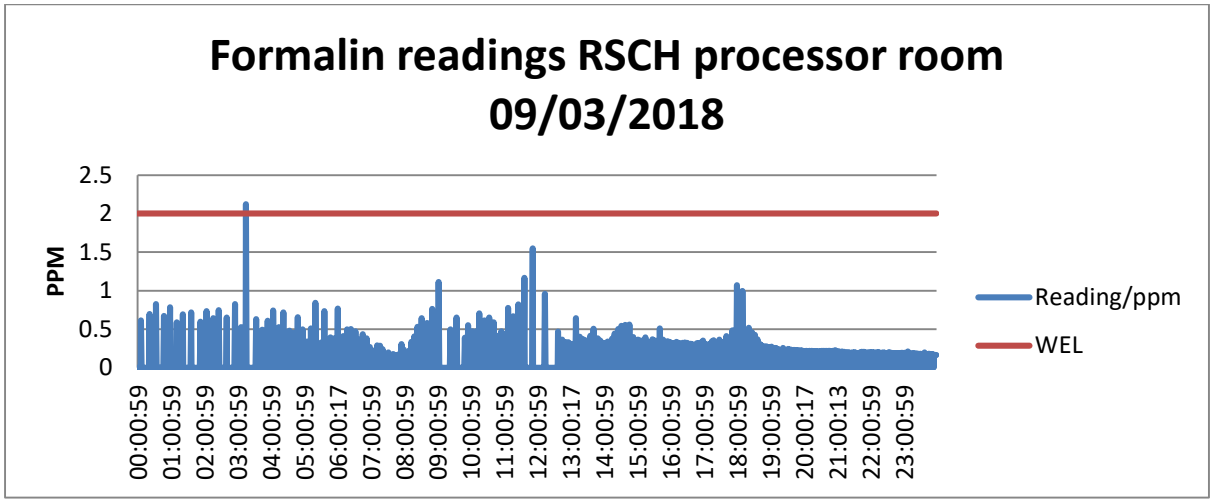

Formalin readings RSCH processor room 04/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

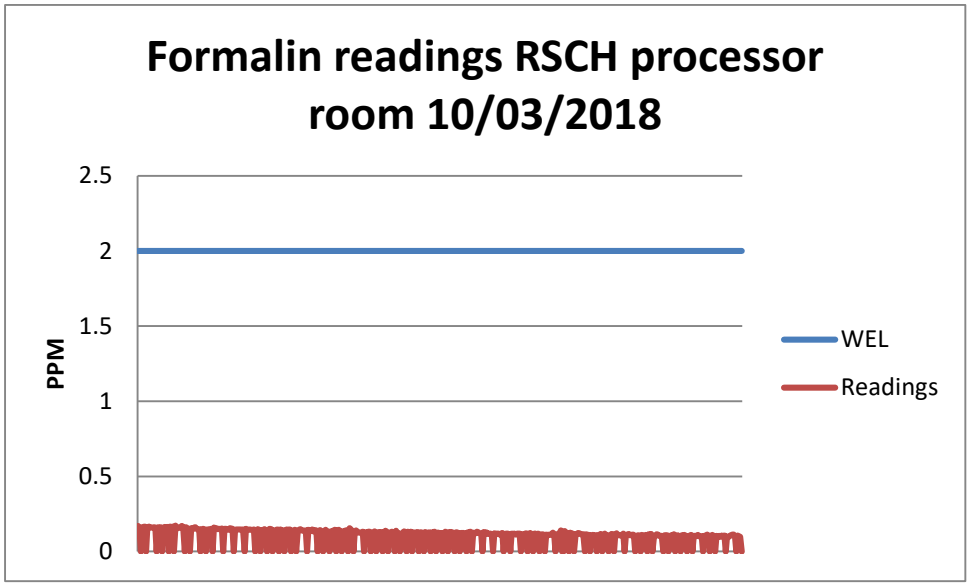

Formalin readings RSCH processor room 05/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

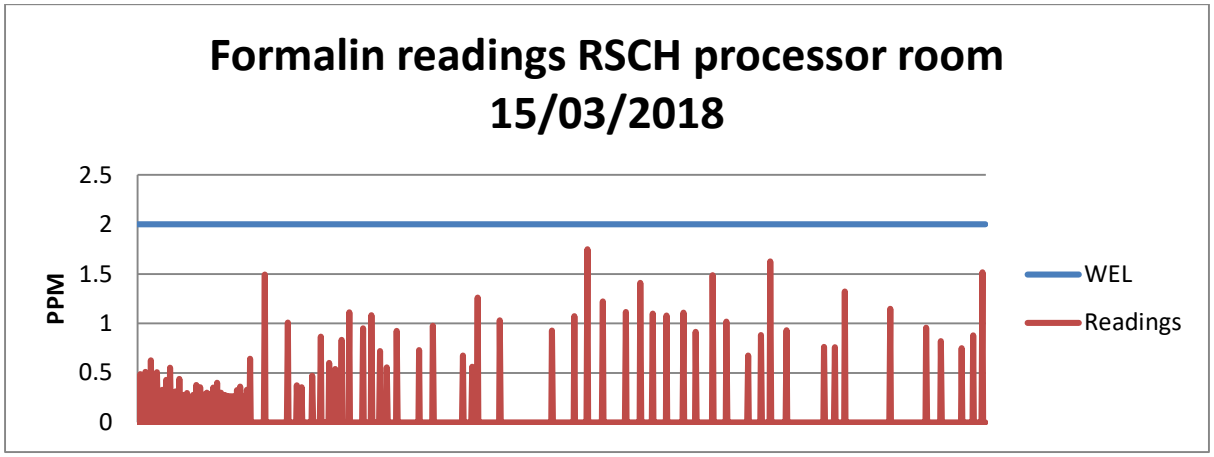

Formalin readings RSCH processor room 06/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

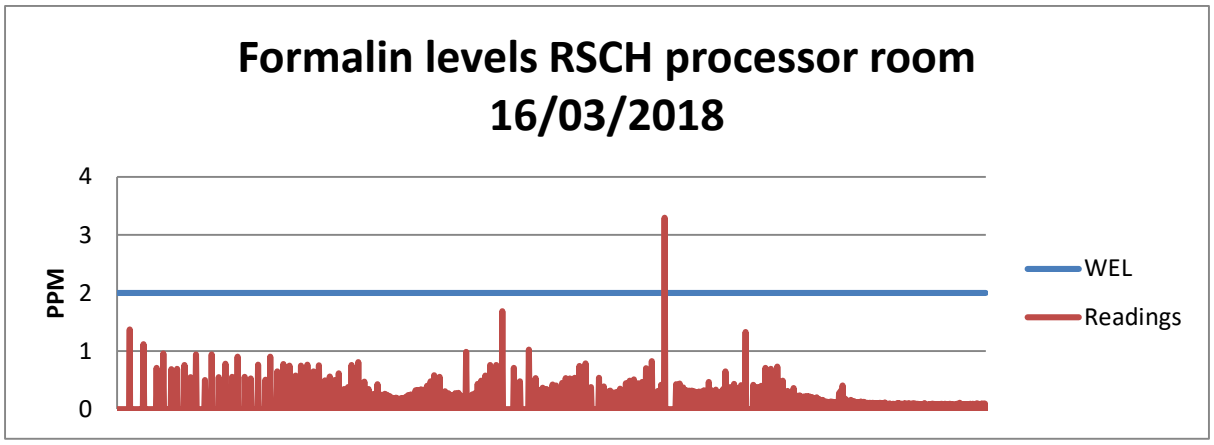

Formalin readings RSCH processor room 07/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

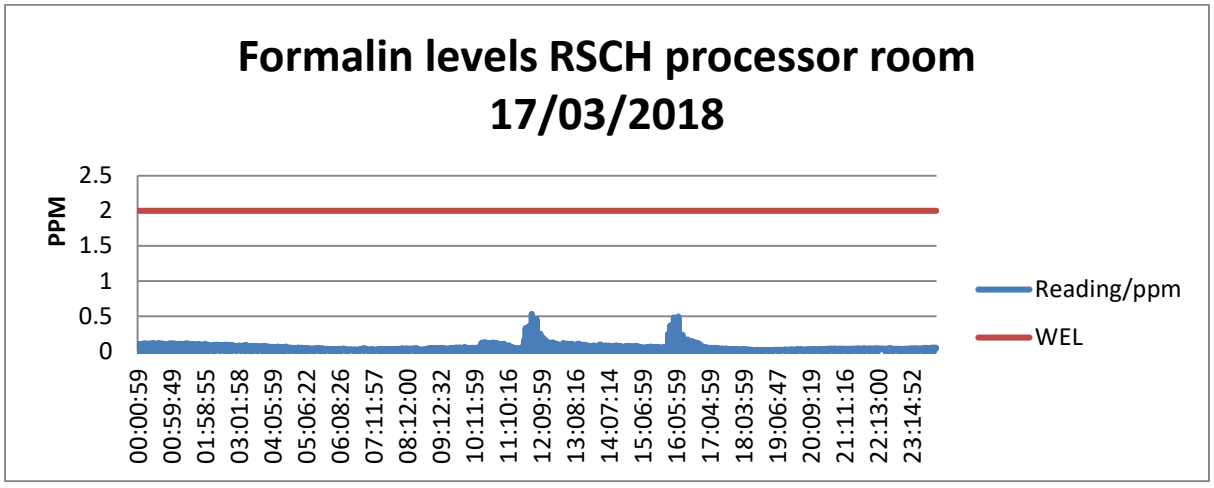

Formalin readings RSCH processor room 08/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

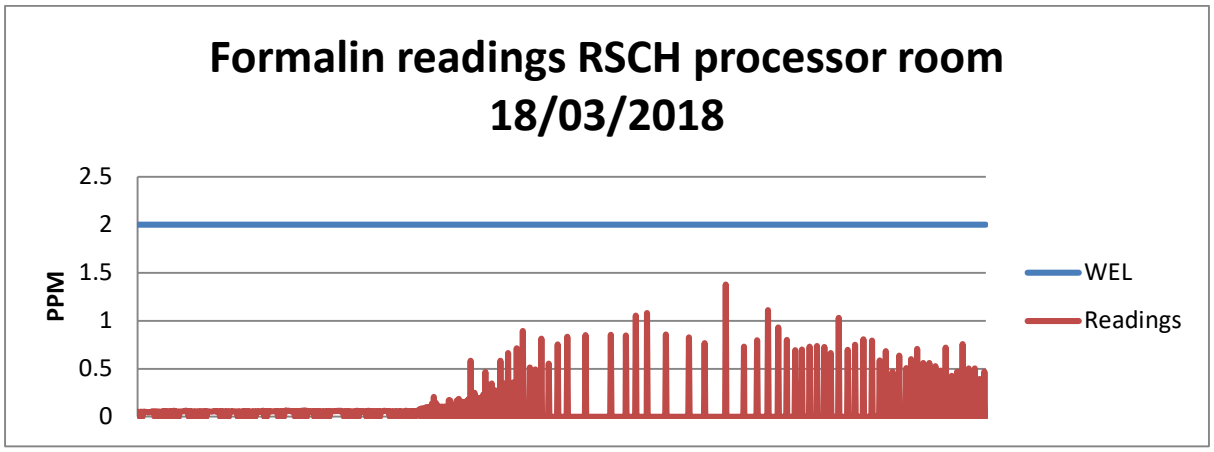

Formalin readings RSCH processor room 09/03/2018
PPM
2.5
2
1.5
1
0.5
0
00:00:59
01:00:59
02:00:59
03:00:59
04:00:59
05:00:59
06:00:17
07:00:59
08:00:59
09:00:59
10:00:59
11:00:59
12:00:59
13:00:17
14:00:59
15:00:59
16:00:59
17:00:59
18:00:59
19:00:59
20:00:17
21:00:13
22:00:59
23:00:59
Reading/ppm
WEL

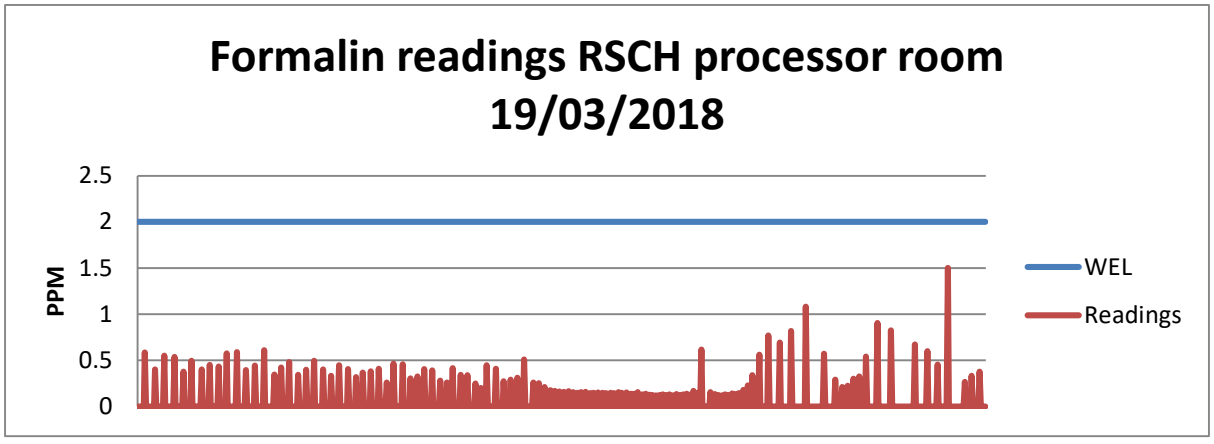

Formalin readings RSCH processor room 10/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

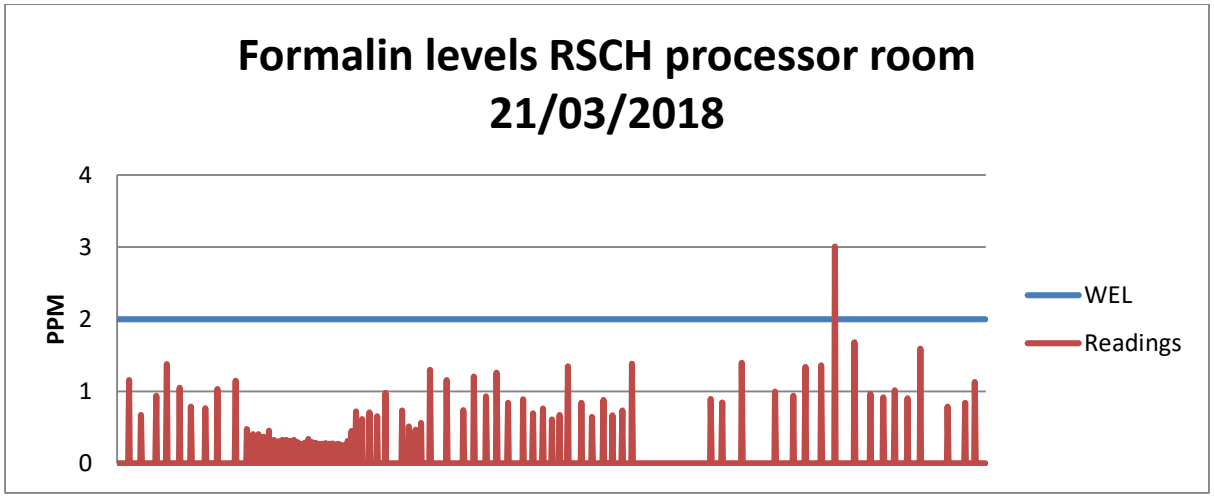

Formalin readings RSCH processor room 15/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

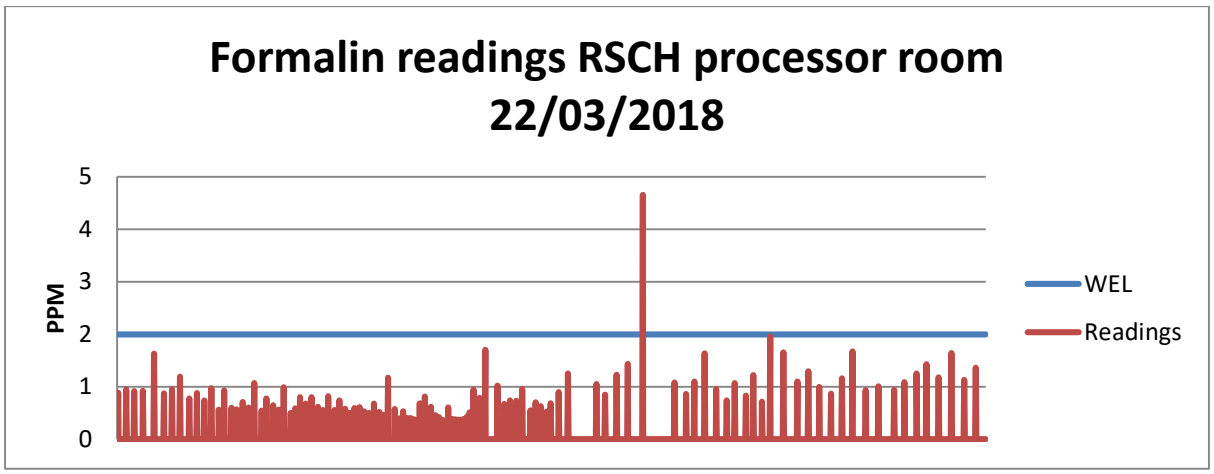

Formalin levels RSCH processor room 16/03/2018
PPM
4
3
2
1
0
WEL
Readings

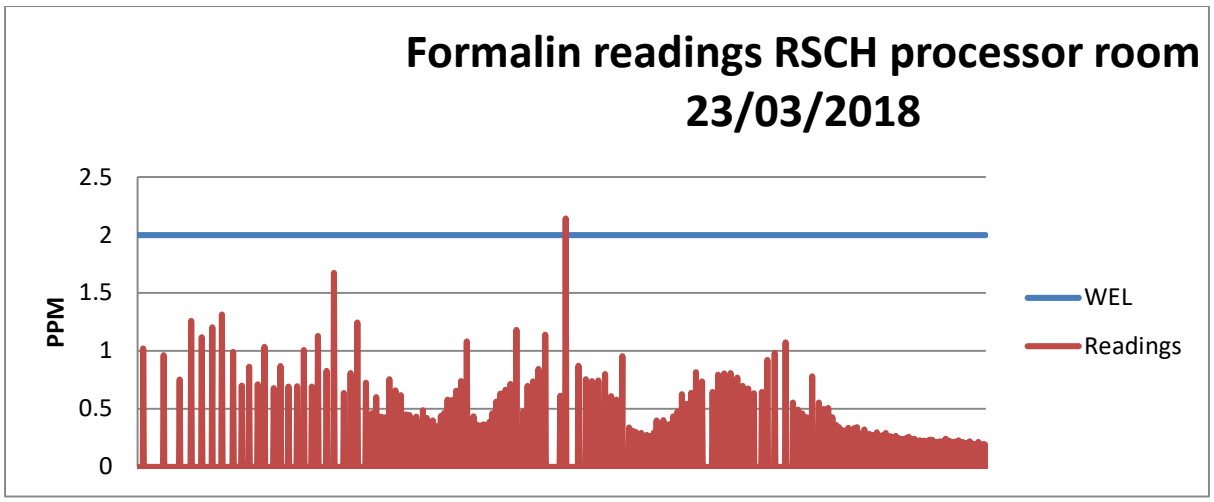

Formalin levels RSCH processor room
17/03/2018
PPM
2.5
2
1.5
1
0.5
0
00:00:59
00:59:49
01:58:55
03:01:58
04:05:59
05:06:22
06:08:26
07:11:57
08:12:00
09:12:32
10:11:59
11:10:16
12:09:59
13:08:16
14:07:14
15:06:59
16:05:59
17:04:59
18:03:59
19:06:47
20:09:19
21:11:16
22:13:00
23:14:52
Reading/ppm
WEL

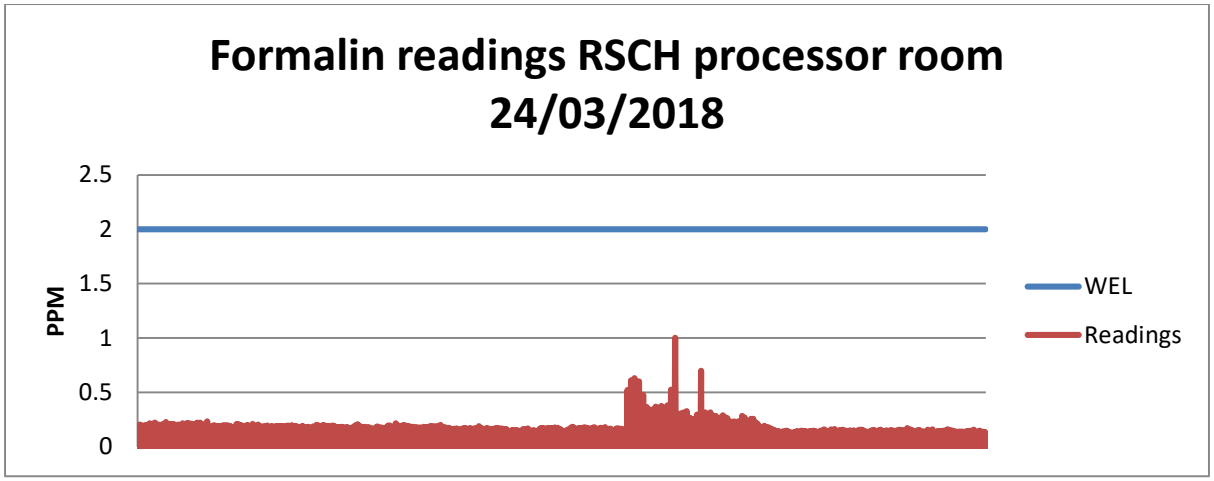

Formalin readings RSCH processor room
18/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

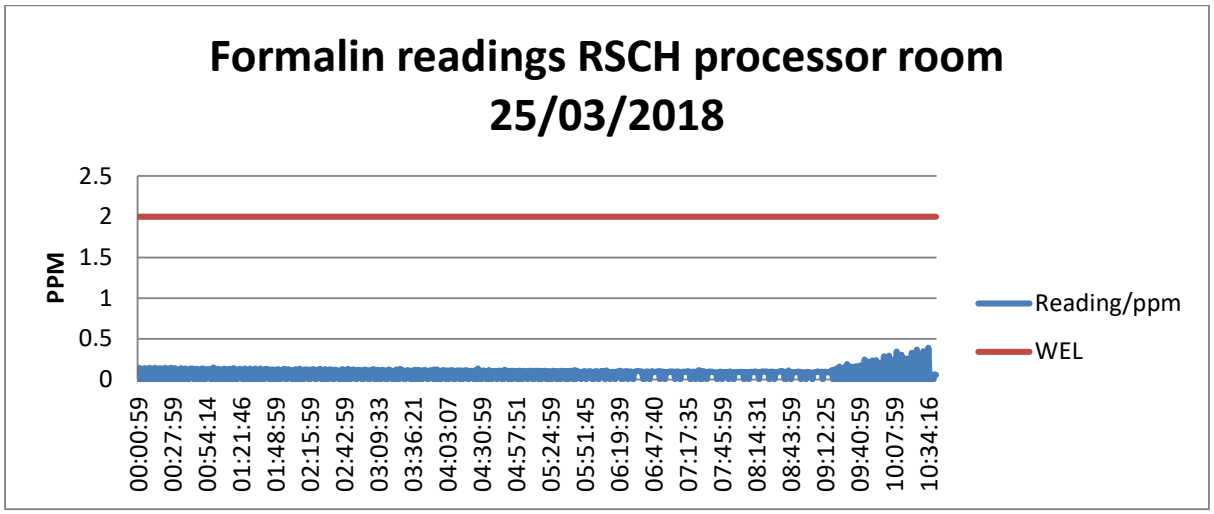

Formalin readings RSCH processor room
19/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

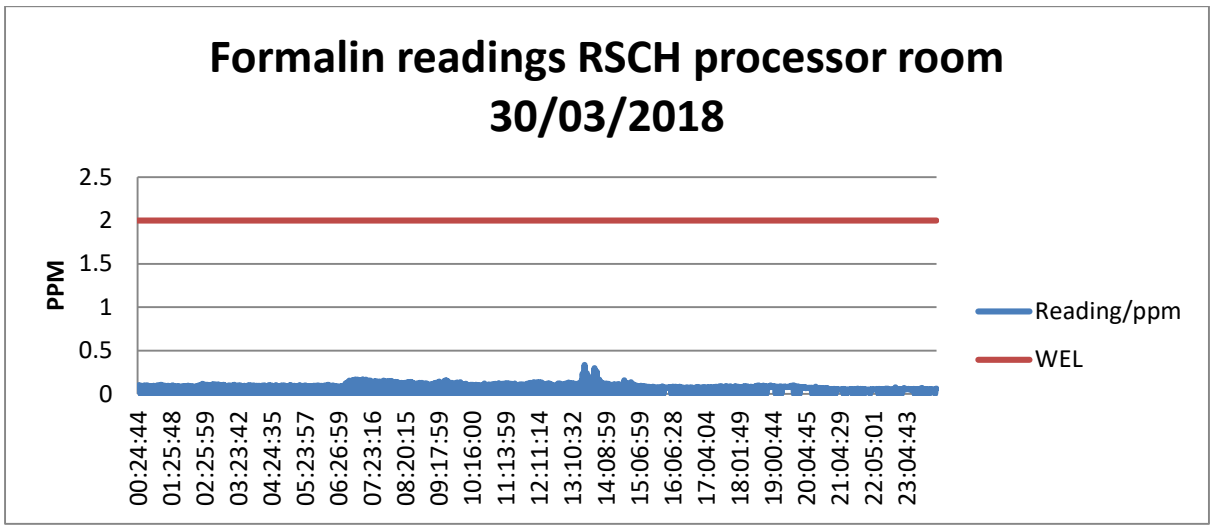

Formalin levels RSCH processor room
21/03/2018
PPM
4
3
2
1
0
WEL
Readings

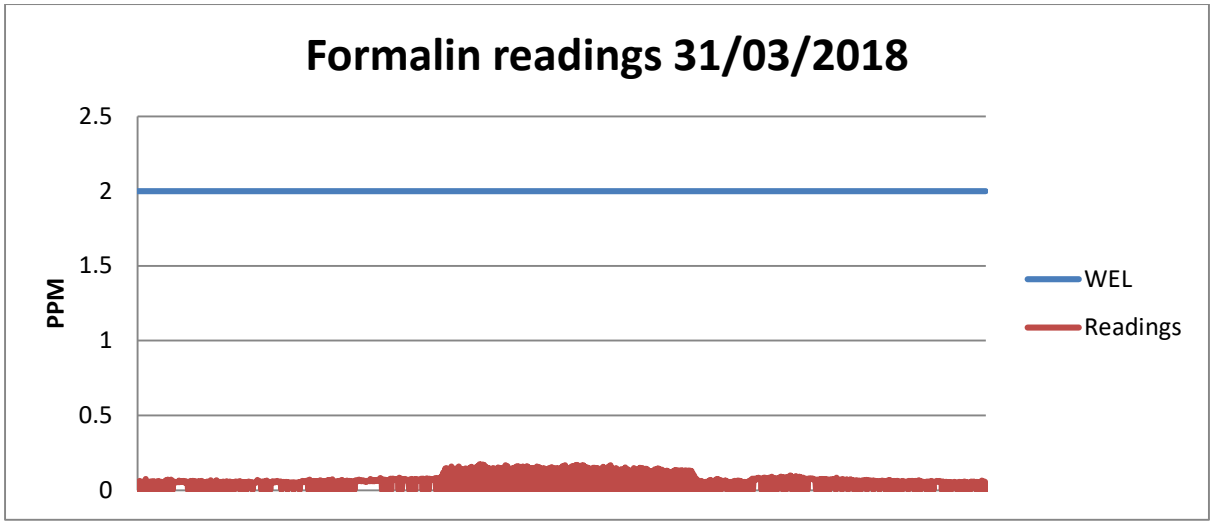

Formalin readings RSCH processor room
22/03/2018
PPM
5
4
3
2
1
0
WEL
Readings

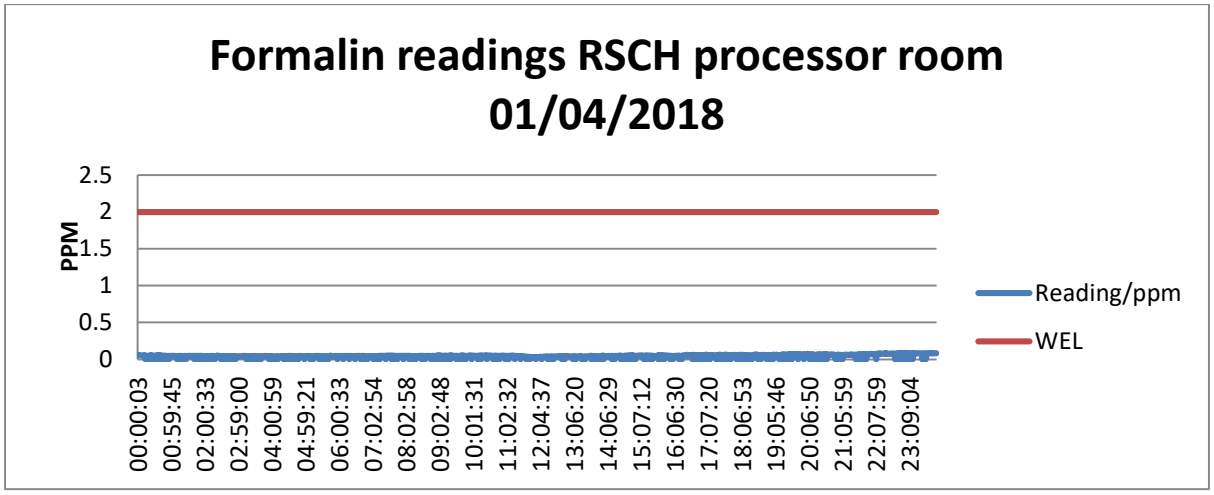

Formalin readings RSCH processor room
23/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

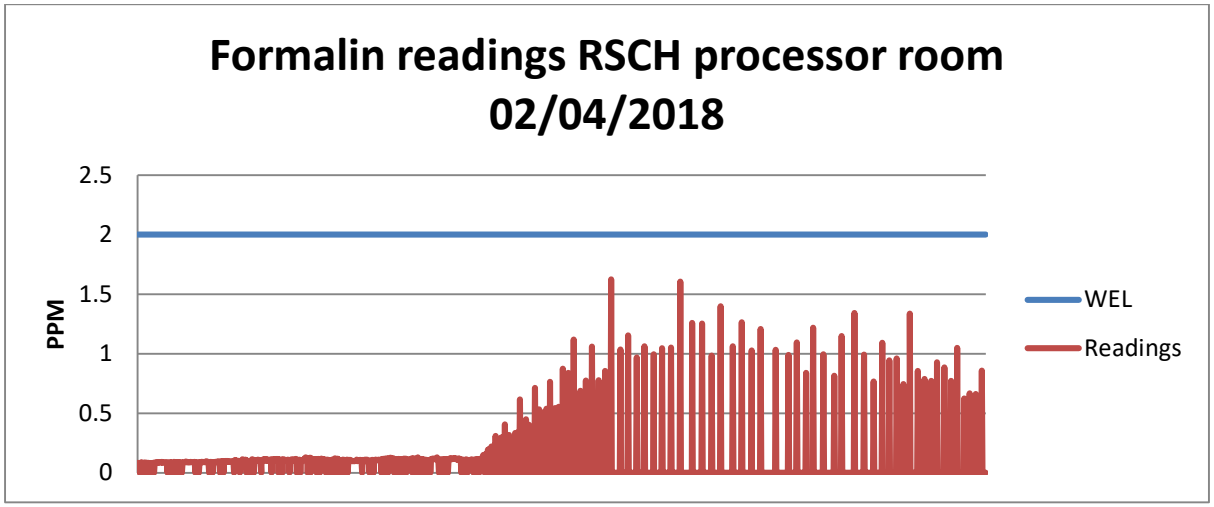

Formalin readings RSCH processor room 24/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

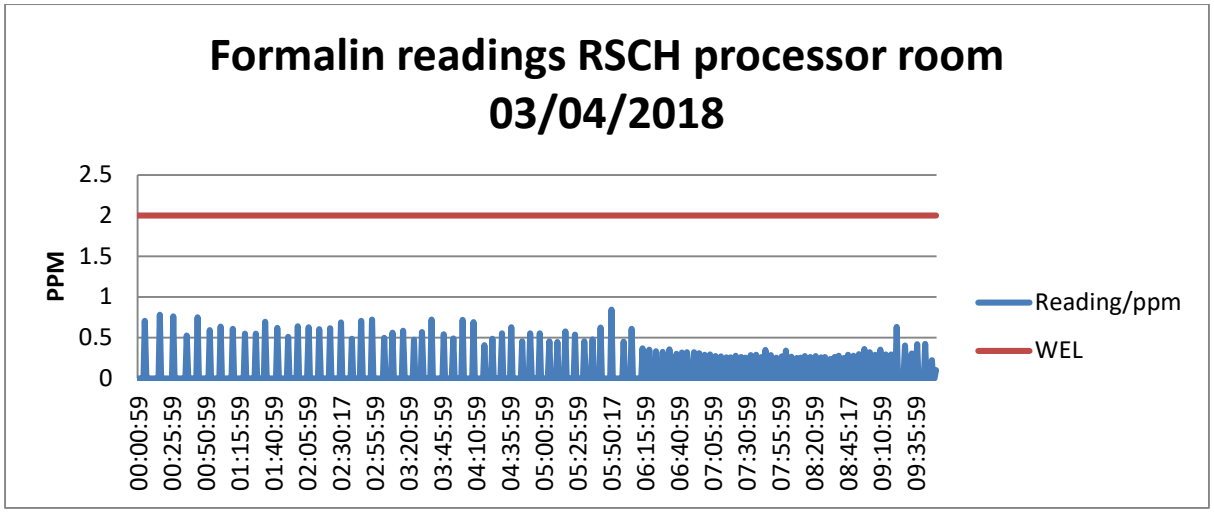

Formalin readings RSCH processor room 25/03/2018
PPM
2.5
2
1.5
1
0.5
0
00:00:59
00:27:59
00:54:14
01:21:46
01:48:59
02:15:59
02:42:59
03:09:33
03:36:21
04:03:07
04:30:59
04:57:51
05:24:59
05:51:45
06:19:39
06:47:40
07:17:35
07:45:59
08:14:31
08:43:59
09:12:25
09:40:59
10:07:59
10:34:16
Reading/ppm
WEL

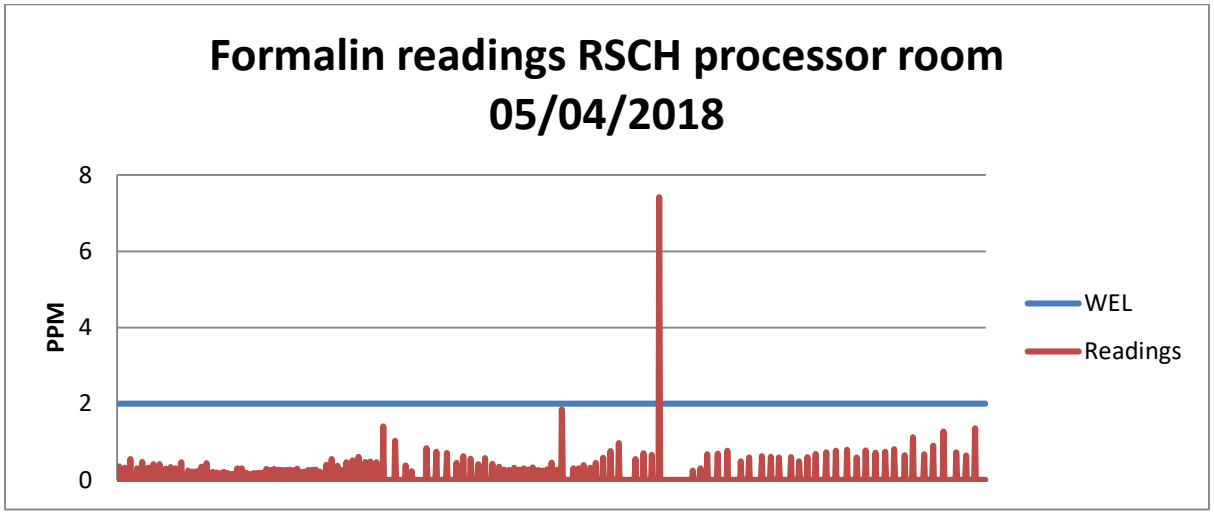

Formalin readings RSCH processor room 30/03/2018
PPM
2.5
2
1.5
1
0.5
0
00:24:44
01:25:48
02:25:59
03:23:42
04:24:35
05:23:57
06:26:59
07:23:16
08:20:15
09:17:59
10:16:00
11:13:59
12:11:14
13:10:32
14:08:59
15:06:59
16:06:28
17:04:04
18:01:49
19:00:44
20:04:45
21:04:29
22:05:01
23:04:43
Reading/ppm
WEL

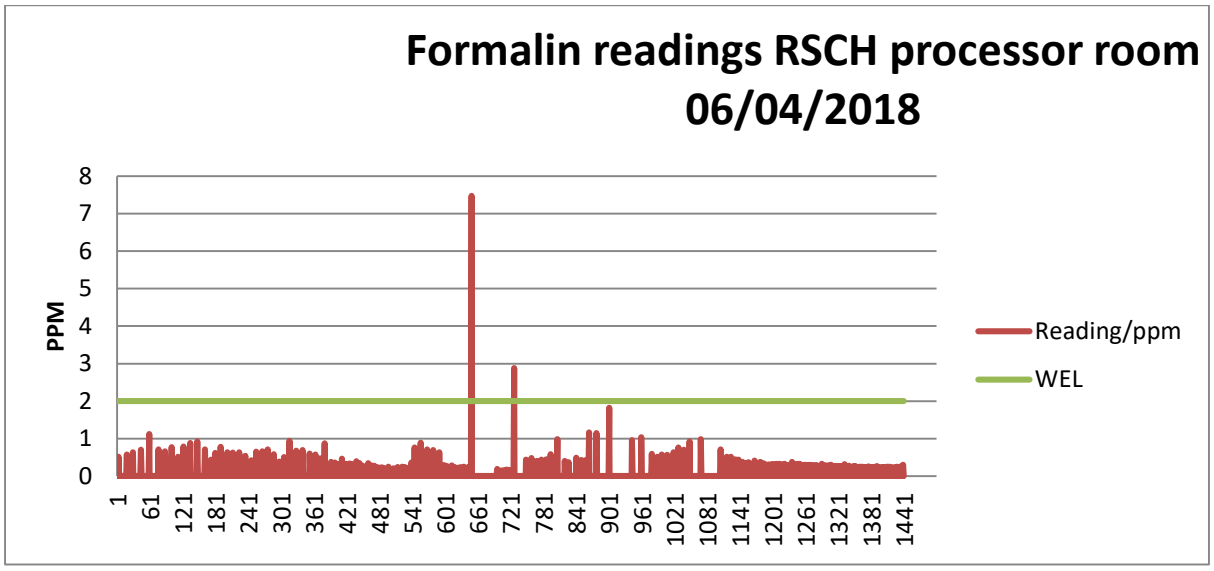

Formalin readings 31/03/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

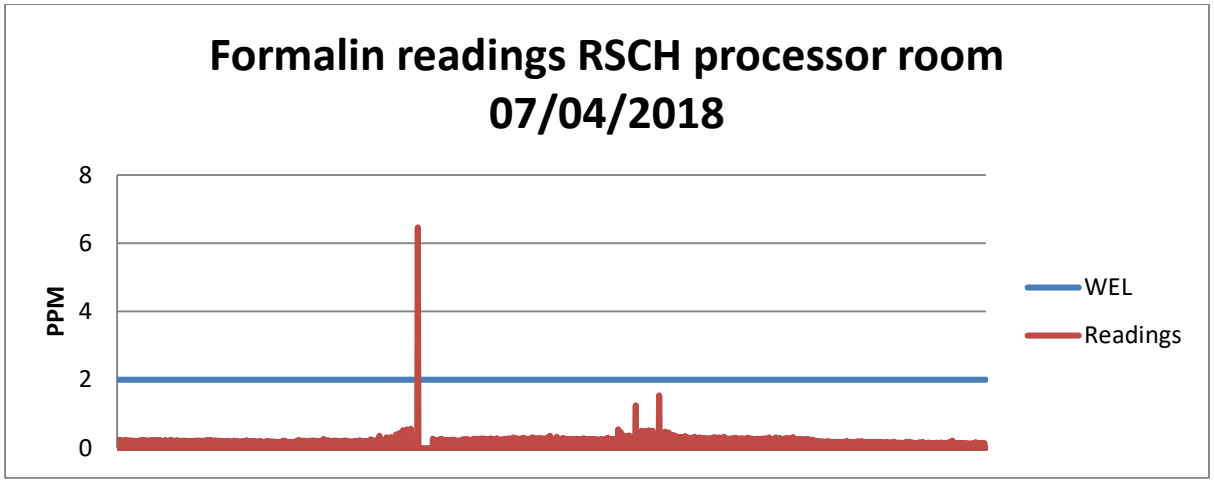

Formalin readings RSCH processor room 01/04/2018
PPM
2.5
2
1.5
1
0.5
0
00:00:03
00:59:45
02:00:33
02:59:00
04:00:59
04:59:21
06:00:33
07:02:54
08:02:58
09:02:48
10:01:31
11:02:32
12:04:37
13:06:20
14:06:29
15:07:12
16:06:30
17:07:20
18:06:53
19:05:46
20:06:50
21:05:59
22:07:59
23:09:04
Reading/ppm
WEL

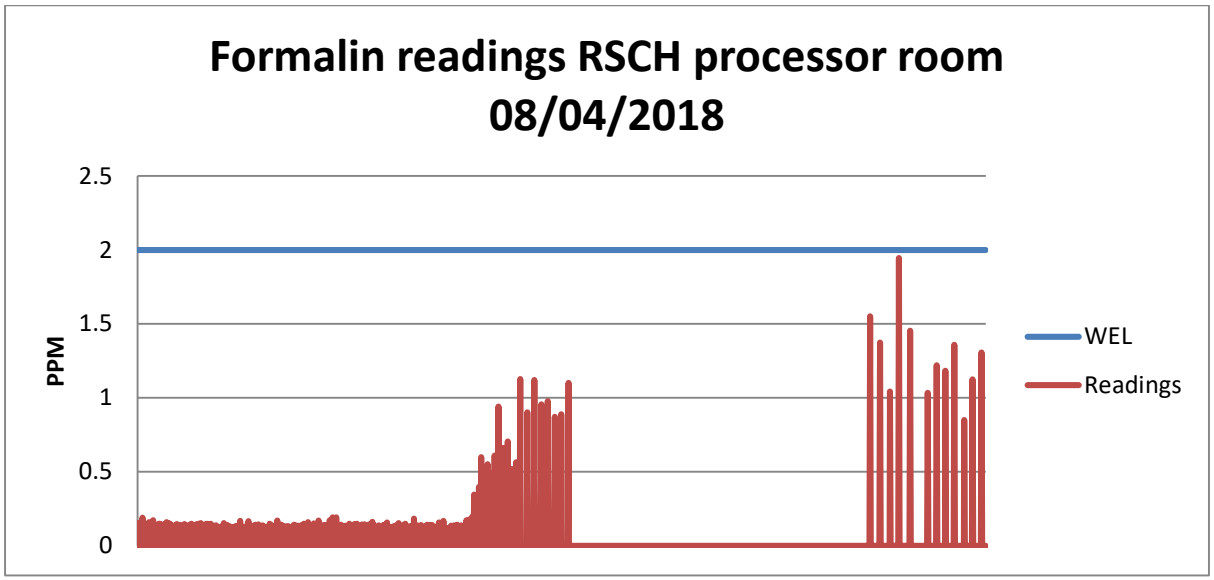

Formalin readings RSCH processor room 02/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

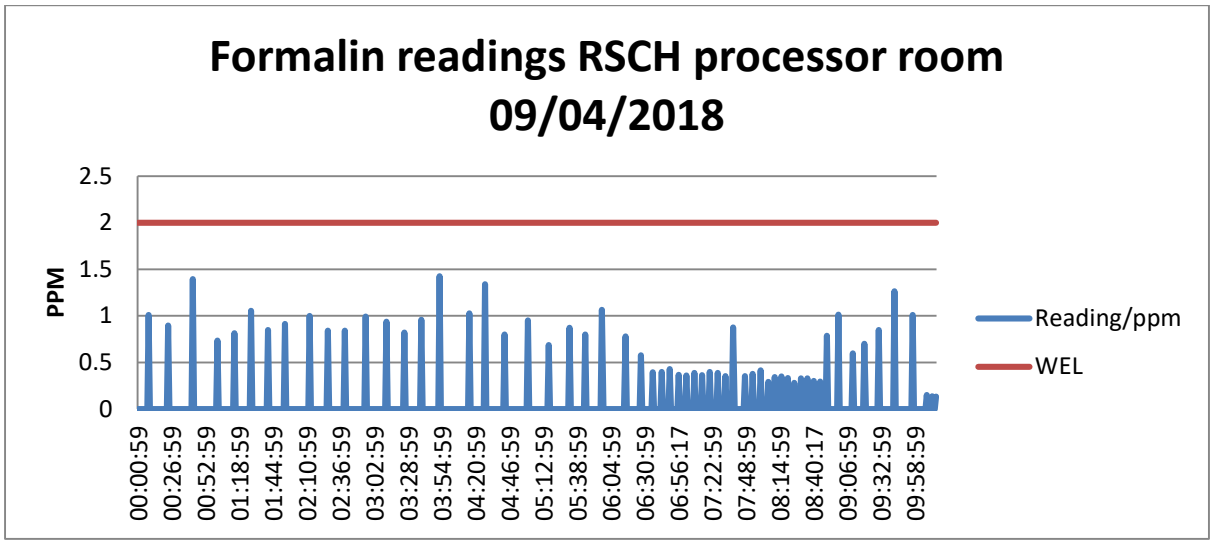

Formalin readings RSCH processor room
03/04/2018
PPM
2.5
2
1.5
1
0.5
0
00:00:59
00:25:59
00:50:59
01:15:59
01:40:59
02:05:59
02:30:17
02:55:59
03:20:59
03:45:59
04:10:59
04:35:59
05:00:59
05:25:59
05:50:17
06:15:59
06:40:59
07:05:59
07:30:59
07:55:59
08:20:59
08:45:17
09:10:59
09:35:59
Reading/ppm
WEL

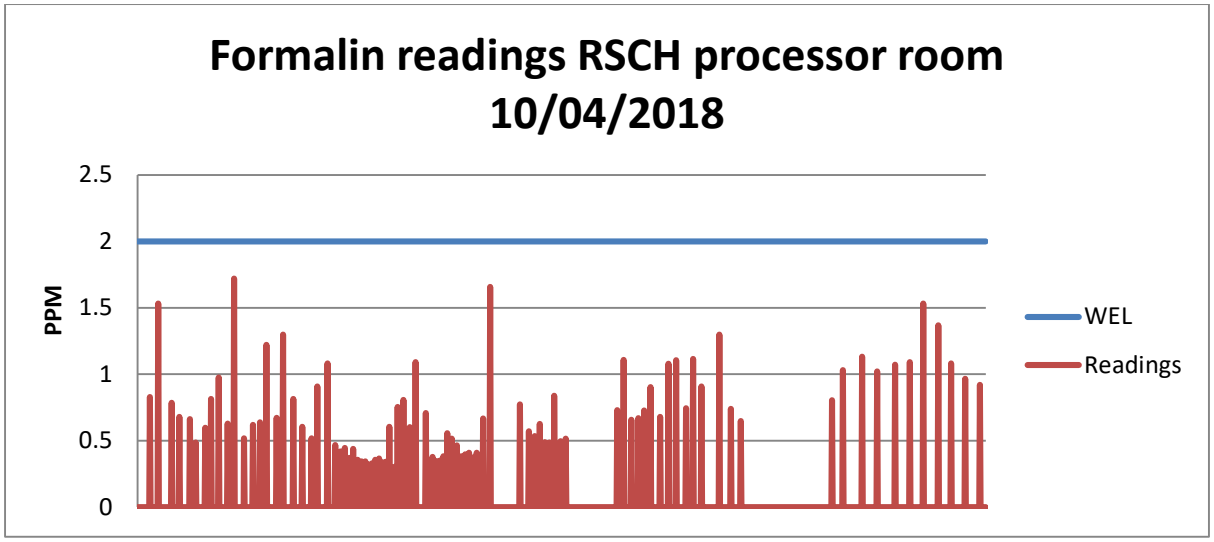

Formalin readings RSCH processor room
05/04/2018
PPM
8
6
4
2
0
WEL
Readings

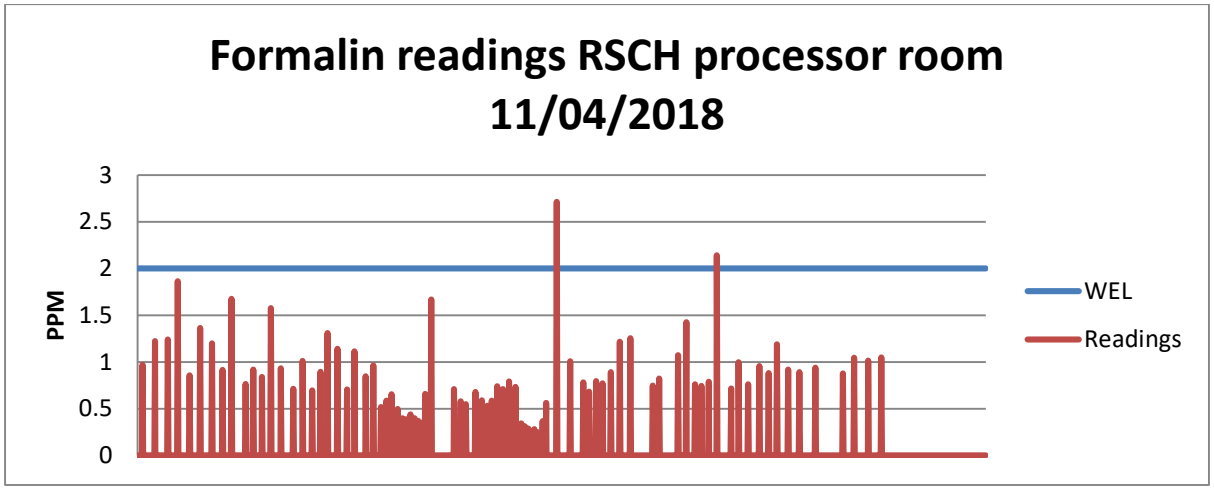

Formalin readings RSCH processor room
06/04/2018
PPM
8
7
6
5
4
3
2
1
0
1
61
121
181
241
301
361
421
481
541
601
661
721
781
841
901
961
1021
1081
1141
1201
1261
1321
1381
1441
Reading/ppm
WEL

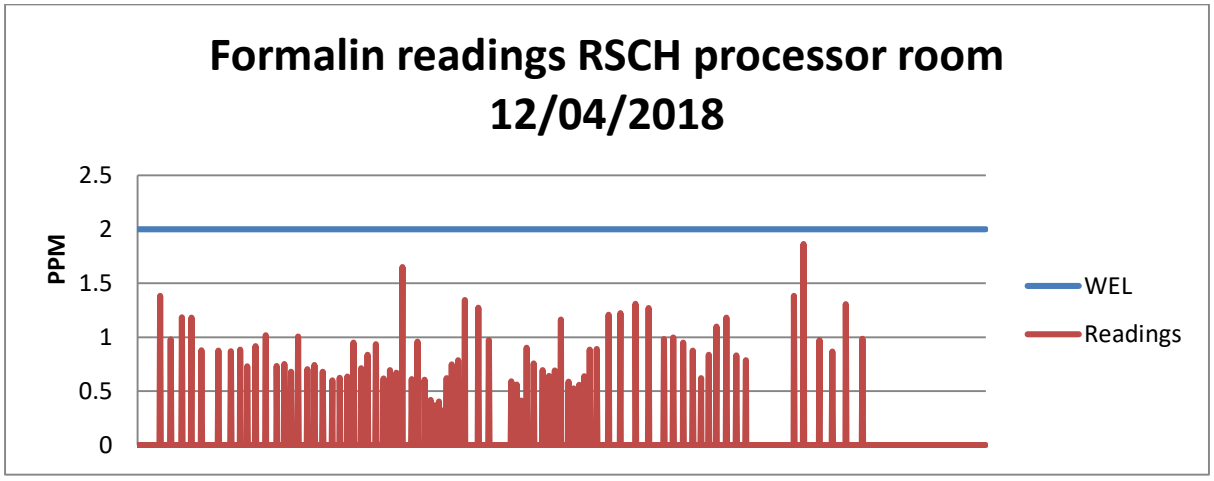

Formalin readings RSCH processor room
07/04/2018
PPM
8
6
4
2
0
WEL
Readings

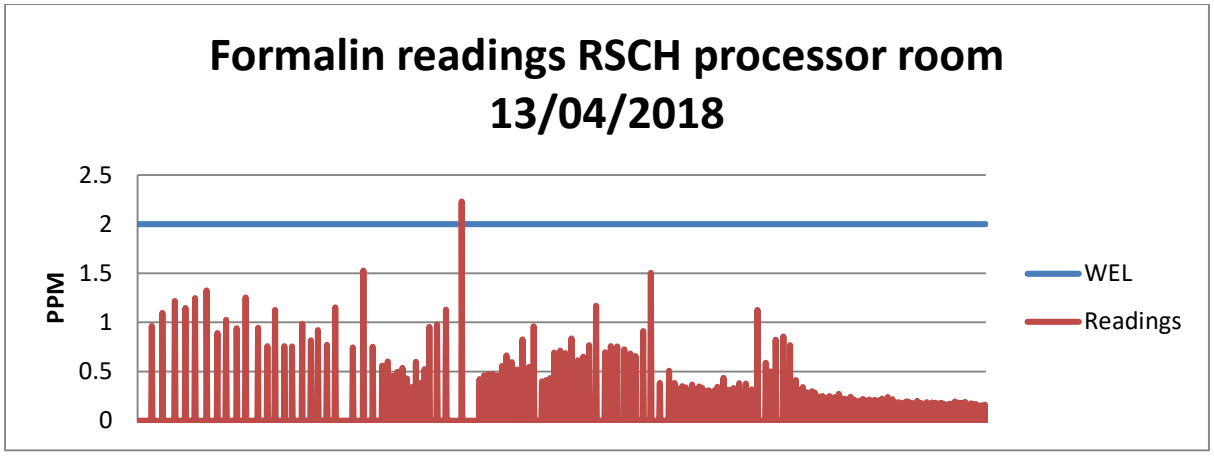

Formalin readings RSCH processor room
08/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

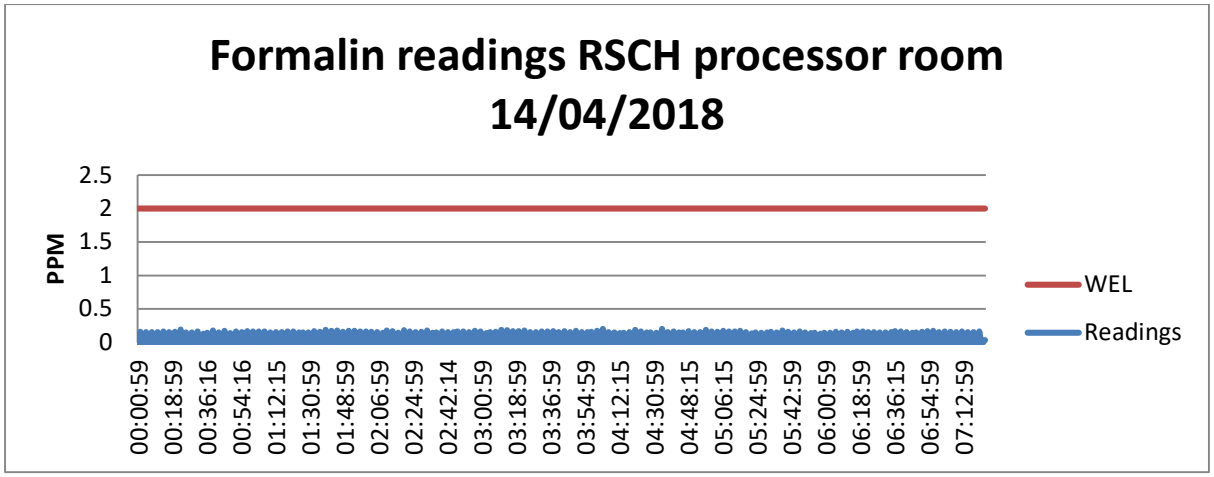

Formalin readings RSCH processor room
09/04/2018
PPM
2.5
2
1.5
1
0.5
0
00:00:59
00:26:59
00:52:59
01:18:59
01:44:59
02:10:59
02:36:59
03:02:59
03:28:59
03:54:59
04:20:59
04:46:59
05:12:59
05:38:59
06:04:59
06:30:59
06:56:17
07:22:59
07:48:59
08:14:59
08:40:17
09:06:59
09:32:59
09:58:59
Reading/ppm
WEL

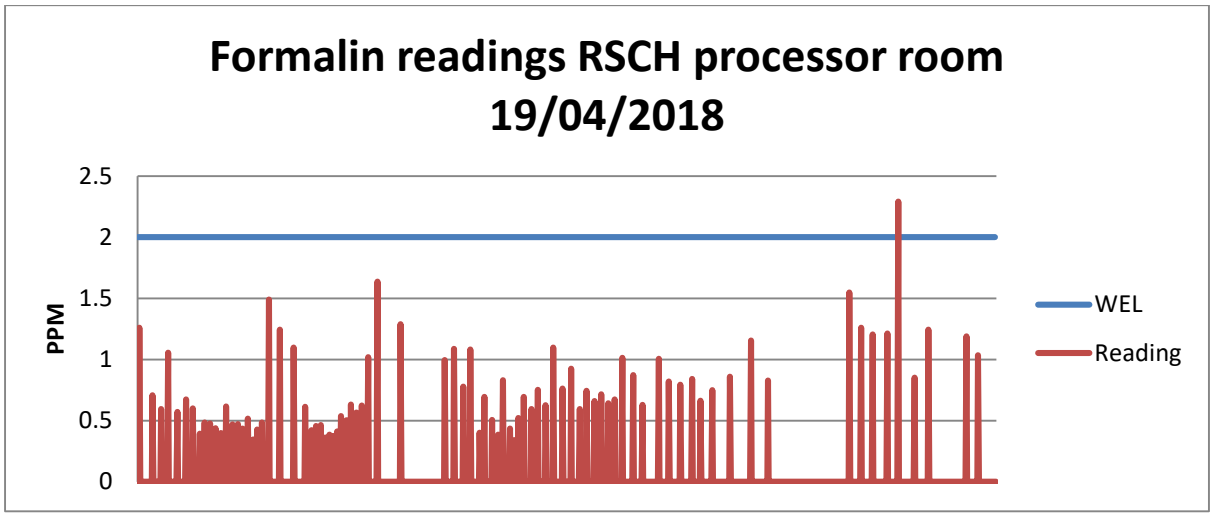

Formalin readings RSCH processor room 10/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

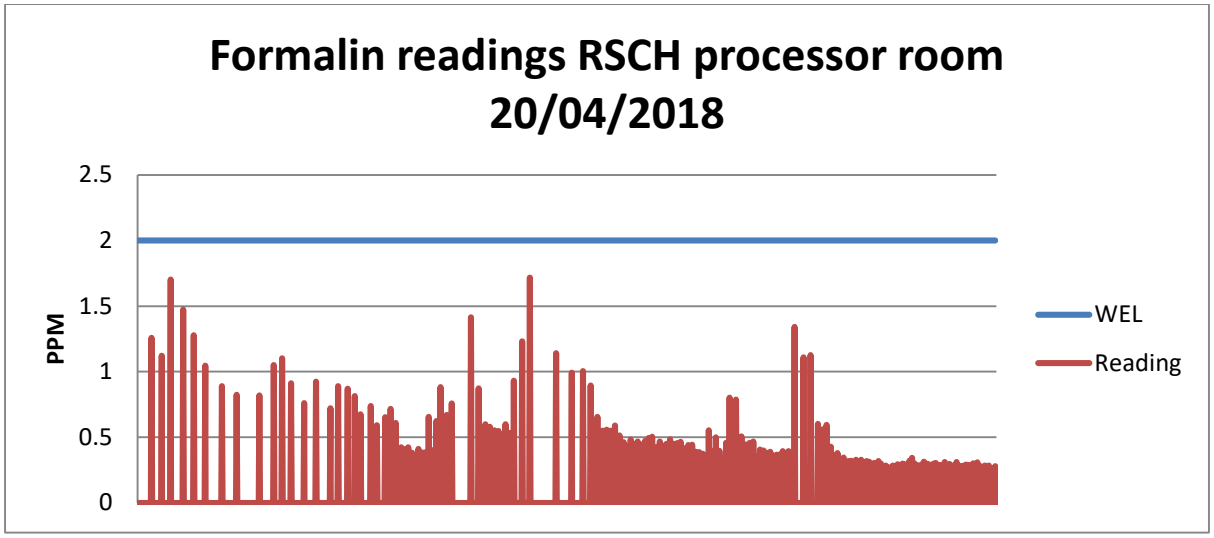

Formalin readings RSCH processor room 11/04/2018
PPM
3
2.5
2
1.5
1
0.5
0
WEL
Readings

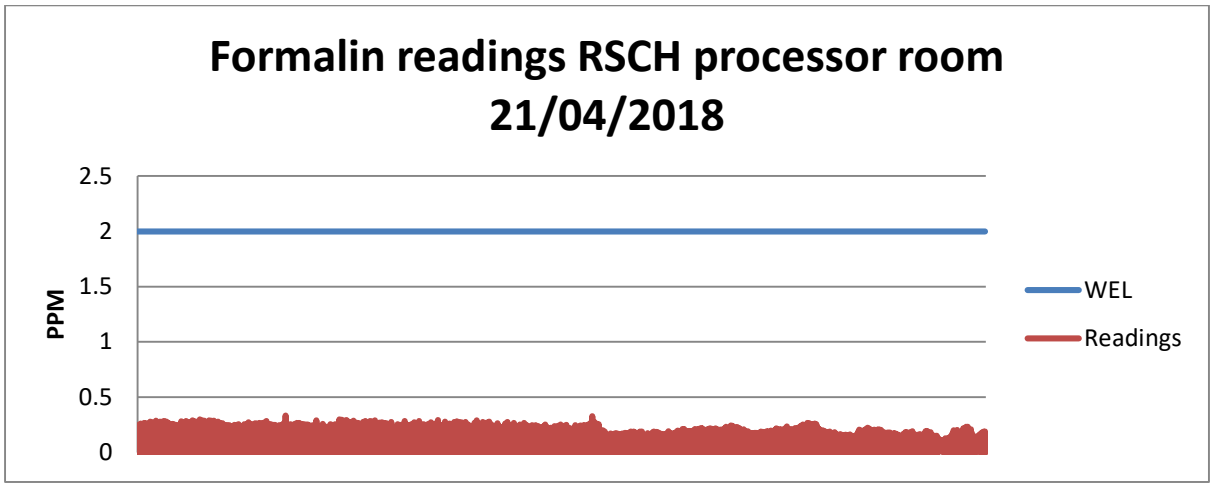

Formalin readings RSCH processor room 12/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings

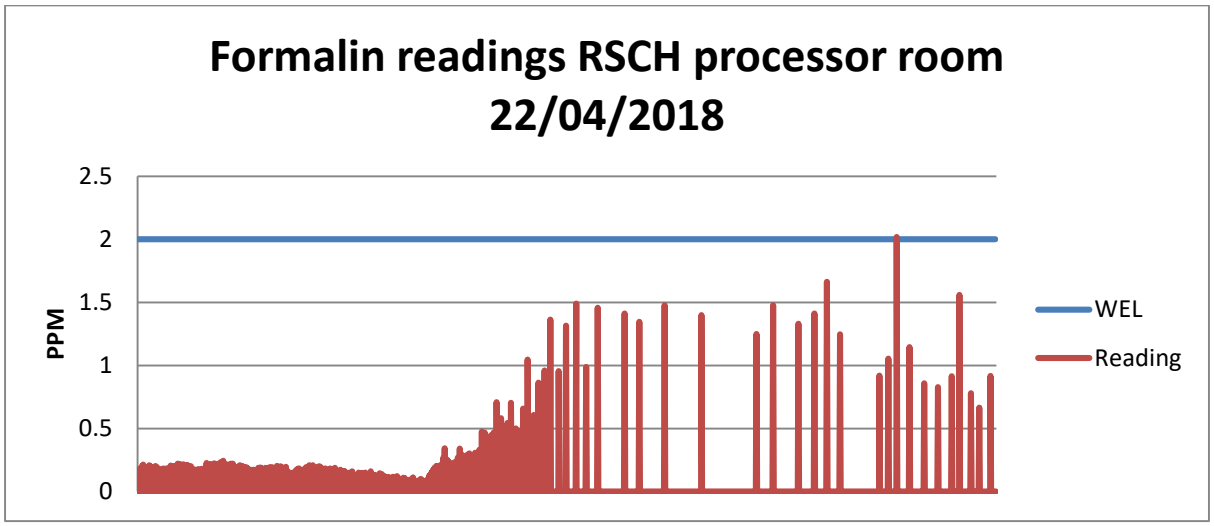

Formalin readings RSCH processor room 13/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings


Formalin readings RSCH processor room 14/04/2018
PPM
2.5
2
1.5
1
0.5
0
00:00:59
00:18:59
00:36:16
00:54:16
01:12:15
01:30:59
01:48:59
02:06:59
02:24:59
02:42:14
03:00:59
03:18:59
03:36:59
03:54:59
04:12:15
04:30:59
04:48:15
05:06:15
05:24:59
05:42:59
06:00:59
06:18:59
06:36:15
06:54:59
07:12:59
WEL
Readings


Formalin readings RSCH processor room 19/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Reading


Formalin readings RSCH processor room 20/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Reading


Formalin readings RSCH processor room 21/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Readings


Formalin readings RSCH processor room 22/04/2018
PPM
2.5
2
1.5
1
0.5
0
WEL
Reading

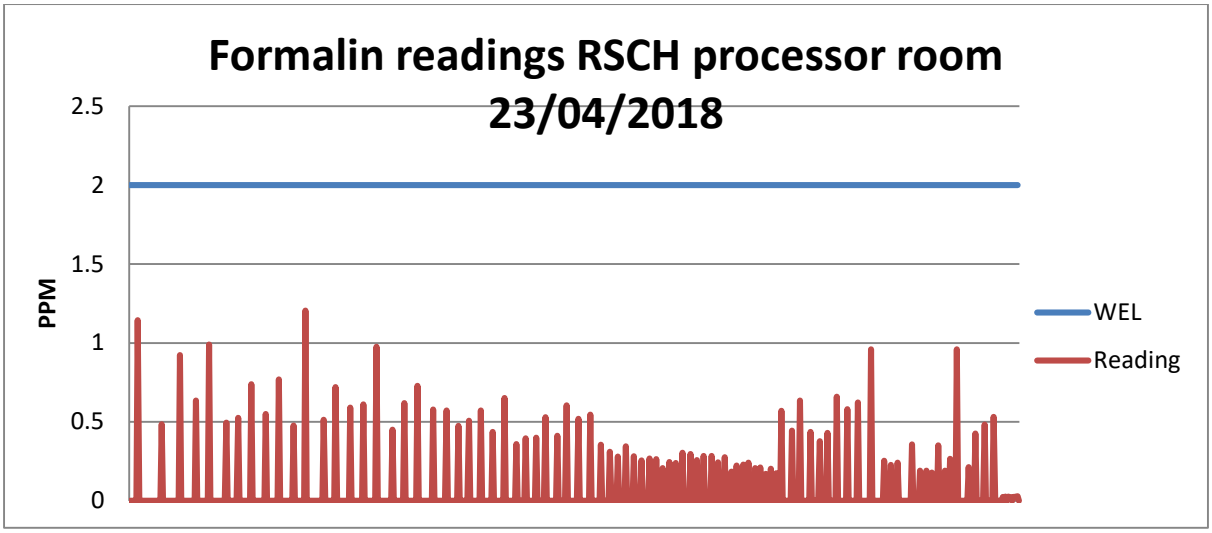


Table 5 shows a summary of WEL breaches recorded from the point at which the Biokker unit was rotated to the end of the trial.

Table 5: WEL breaches recorded by the HtV-M formaldemeter in the RSCH tissue processor room during the monitoring period of 28/02/2018 to 23/04/2018

Date:	Time of breach:	PPM:	Time of next reading:	PPM:	Time at which PPM <2	PPM:	Total time (mins)
07/03/18	15.34	2.055	15.55	0.886			11
09/03/18	03.15	2.124	03.33	0.63			18
16/03/18	15.07	3.295	15.26	0.428			19
21/03/18	20.40	3.005	21.06	1.681			26
22/03/18	15.07	4.657	16.02	1.085			55
23/03/18	12.36	2.142	12.57	0.817			21
05/04/18	16.43	7.417	17.28	0.25			45
06/04/18	10.48	7.479	11.35	0.189			47
	12.06	2.881	12.28	0.442			22
07/04/18	08.18	6.467	08.43	0.273			25
11/04/18	11.51	2.713	12.14	1.009			23
	16.23	2.142	16.47	0.715			24
13/04/18	09.10	2.229	09.40	0.422			30
19/04/18	21.53	2.291	22.14	0.851			21
22/04/18	21.13	2.017	21.34	1.144			21

15 breaches were recorded from 28/02/2018 to 23/04/2018, one of which was less than 15 minutes. When compared to the week of 15/01/2018 where 26 breaches were recorded in a single week, this shows a definite reduction in the number of breaches observed.

Formaldehyde levels were also measured in the processor room using an Airchek badge as shown in table 6 below:

Table 6: Airchek badge readings for cut-up area and processing room.

Date:	Time:	Activity performed:	Length of time badge worn for:	Reading:
16/04/18	17.30pm	Sorting blocks for processing	15 mins (STEL)	0.18ppm
16/04/18	18.00pm	Loading processors	15 mins (STEL)	0.14ppm
18/04/18	09.30am – 18.30pm	All areas of lab, ie cut up bench, processor room etc	8 hrs (TWA)	0.052ppm

As shown in table 6 above, during an 8 hour analysis of the processing room on 18/04/2018, formalin levels were not detected to have breached.

Limitations of the study:

When the formaldemeter detects high levels of formaldehyde, it can sometimes require a period of time to 're-set' before taking another reading. This poses difficulty in interpreting the data as it is not always possible to say whether a breach truly lasted longer than 15 minutes. It could often be the case that levels had indeed dropped below 2ppm within 15 minutes, but there are not always readings taken to confirm this.

In discussions with Surrey Diagnostics, it was explained that the Biokker unit cannot prevent sudden rises of formaldehyde levels occurring, but it can help to reduce them quickly, thus returning to safe levels as soon as possible.

Bearing this in mind and analysing the data from this study, it is felt that after the Biokker unit was installed (and particularly after it was re-positioned) the readings taken directly after the initial breach are lower than pre-installation, and were most likely within safe limits within the 15 minute timeframe (although due to the limitations of the formaldemeter this cannot be confirmed).

Conclusion and recommendation:

Monitoring of formaldehyde levels using a formaldemeter and Airchek badges gives a retrospective analysis, which does not really help with keeping the working environment safe for staff on a daily basis. Options for effective CAPA can be limited, affected by space or financial constraints. Data from the formaldemeter can sometimes be difficult to interpret due to periods of down-time whilst it re-sets. Airchek badge reports take around 3 weeks to

be returned, meaning that non-conformities are being raised for breaches that happened some time ago.

Utilising technology such as the Biokker unit can help to reduce formaldehyde levels in the air on an on-going, prospective basis, and can be monitored for effectiveness using the formaldemeter / badge system. It also has wider applications within the laboratory for other chemicals such as xylene. It is wall-mounted and therefore does not require a great deal of space. There is no daily maintenance required.

It is recommended that a unit is purchased for use within the RSCH processing room to help keep formaldehyde levels under 2ppm and quickly reduce any breaches back to within safe limits.

References:

1. https://www.sevron.co.uk/msds/formal-saline-msds-download2
2. Bancroft, J.D (2012) Theory and Practice of Histological Techniques, 7th edition
3. http://www.afosgroup.com/medical/why-afos-medical
4. http://www.ppm-technology.com/formaldemeter%20htv-m.htm
5. EH40/2005 Workplace Exposure Limits, 2011, HSE
6. https://www.leicabiosystems.com/histology-consumables/safety-hygiene-products/chemical-control/products/airchek-badges/
7. http://surrey-diagnostics.co.uk/environmental-services/