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USE OF A CARBON DIOXIDE MEASUREMENT SYSTEM TO CONTROL THE PROCESS OF OBTAINING BREATHING AIR FOR HYPERBARIC OXYGEN CONDITIONS

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ABSTRACT

Maintaining a stable carbon dioxide content in the process of producing breathing air is important both for the safety of divers performing underwater work and for avoiding financial losses resulting from poor product quality. This paper deals with the implementation of safety measurement systems for online control of the breathing air production process. On the basis of a qualified control system, the capability of the rationalised process was assessed, identifying both its current status and its potential for improvement in terms of eliminating defects caused by excessive carbon dioxide content. For process reasons, the effectiveness of online process monitoring was evaluated against the previously used periodic sample control by means of laboratory methods of instrumental analysis. The analysis was conducted at KTPP AMW[1] for the compressed air supply system of the DGKN - 120[2] complex.

Keywords: process capability, diving breathing air quality, diving gases, measurement systems, process variation, carbon dioxide elimination.

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INTRODUCTION

The quality of the breathing medium is of fundamental importance in maintaining the safety of underwater operations. It also significantly influences the development of technologies for the distribution, production and quality control of breathing air in the processes of supplying hyperbaric facilities. The need to maintain high quality breathing air in the Polish Armed Forces results from the provisions of the applicable national normative requirements: NO-07-A005:2020 [1], NO-52-A201:2012, [2], safety regulations in force in the Polish Armed Forces [3] and NATO[3] standardisation documents , AdivP-04 , AdivP-04 [4,5]. According to the recommendations of the Polish Armed Forces, users should perform tests to confirm the quality of the breathing medium every 3 months or 50 hours of compression and filtration system operation.

Similarly, in the environment of commercial civilian diving, these requirements are regulated by the provisions of the Regulation of the Minister of Infrastructure of 19 May 2004 on health and safety at work in underwater activities Journal of Laws 2004.116.1210[4] [6]. Contrary to the regulations of the Polish Armed Forces, they provide for the necessity of conducting physicochemical composition tests in order to confirm their further usefulness every 6 months. This aspect is also regulated by the requirements of PN-W-88503:1998/Az1:2000 [7] and PN-EN 12021:2014-08 [8].

It has been shown that even the implementation of modern redundant solutions for compression and filtration systems does not ensure adequate capacity of production processes. It has been found that some of the most modern filtration systems are not immune to influences related to the effects of operator non-compliance with SOPs[5], intake of difficult-to-remove contaminants, loss of filter bed properties, etc. [9]. The current state of engineering under operational conditions without the application of appropriate control systems does not allow to achieve higher than 3σ capability of the process to obtain, maintain and distribute breathing air for hyperbaric conditions [10].

The necessity to ensure proper air quality for hyperbaric exposures requires the proper qualification and metrological supervision of the measuring systems in use. From a toxicological and technical risk point of view [11], the safe and effective implementation of hyperbaric exposures is determined by the control of numerous dynamically changing parameters of atmospheric composition, including the proportion of harmful pollutants. The risk assessment process analysis [9] has shown that for the current best available technology for obtaining, holding and distributing breathing air for hyperbaric oxygen conditions, the greatest potential lies in safety systems, either in simple form[6], or as systems[7] equipped with multidimensional sensory[8], expert and actuator systems[9]. It is reasonable to believe that the implementation of online control systems will reduce the risk of process defects materialising.

Proper inference, inspection and control of the production process[10] requires the use of a reliable and useful surveillance tool with proven metrological properties, without which it is not possible to establish a high capability of the production processes of breathing mixtures. The use of adequate measuring equipment is an important element influencing the safety of underwater work by minimising the potential toxicological impact of existing contaminants on the diver's body.

The ad hoc[11] use of indicator tube systems or other portable analysers is insufficient. Their use often leads to erroneous conclusions and incorrect interpretation of the obtained measurement results, and consequently of the state of the monitored process. Portable gas analysers and automatic warning systems implemented in filtration systems allow only incomplete control. According to the requirements of PN-EN ISO 10012 [12], an effective measurement management system should ensure their suitability for the intended use and have a significant impact on the achievement of product and process quality objectives, and therefore should meet the critical quality requirements CTQ[12].

This paper presents an evaluation of the capability of a rationalised breathing air production process using a developed measurement system adapted to online process control. The results of the implementation of the control system are compared with the results of the current approach resulting from the mandatory laboratory control[13].

The research was carried out at the Department of Underwater Works Technology (KTPP AMW) for the compression and filtration system used to supply the Experimental Deep-water Diving Complex ($DGKN-120$)[14].

PROBLEM SITUATION

To date, control measurements of breathing air samples in the production process have been carried out post factum. Laboratory analytical systems were oriented towards measuring relevant output values of critical process parameters downstream of the breathing air filtration system. Tests were performed periodically in accordance with GLP requirements[15] in the respiratory gas physico-chemical laboratory with a frequency of three to six months[16]. Laboratory testing enabled periodic identification of the occurrence of exceedances of the set CTQ requirements. Disclosure of possible defects allowed the ordering party to take action to determine the cause and undertake an appropriate response leading to correction of the supervised system.

Previous research results [13] indicate that even in a responsible and intensively operated systems such a method of supervision, due to observed variability of the process, does not allow for full detection of defects. Although the control system introduced by the user is compliant with the requirements, it does not allow a reliable quality assessment of the product and an appropriate risk management. This system of control provides incomplete detection of process defects. An inadequate measurement management system may lead to the materialisation of risks resulting from inadequate equipment and defective measurement processes. In this case, their defectiveness should be understood as the use of appropriate, validated measurement systems in an inadequate supervisory and control system[17].

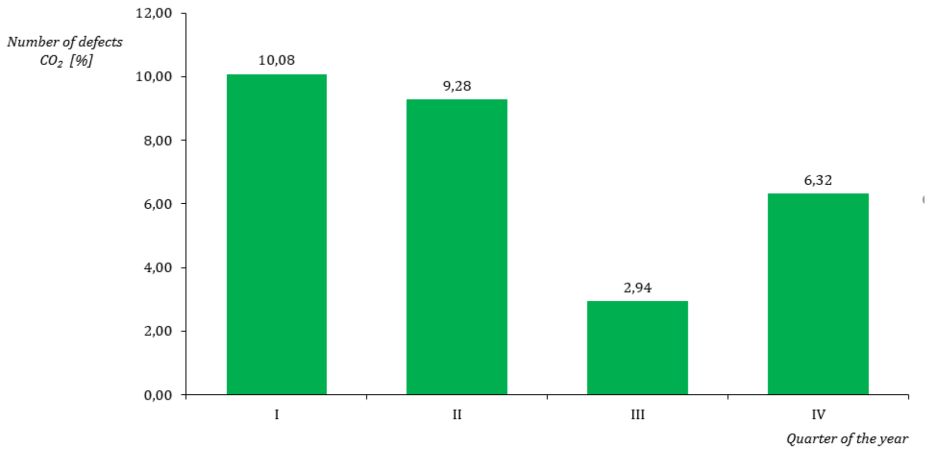


Fig. 1 Occurrence in years 2018÷2019 $C_{CO_2} \geq 500ppm \approx 10{,}08\%(2{,}78\sigma) > USL$ production process defects for Class II breathing air acc. to NO-07-A005:2010 revealed by periodic laboratory analysis. Source: own study on the basis of data obtained in the Physico-Chemical Laboratory of $WTM\ Gdynia\ 1\ RBlog$.

Disclosure of about 10%[18] (2,78σ) of process defects during laboratory testing, due to exceeding CO_2 content in the control sample, generated excessive financial losses[19] and cyclic periodic shutdowns of compression systems – Figure 1. In view of the above, supplementing the 3-month laboratory periodic supervision with performance tests by means of automated online control systems was considered.

In contrast to the exploitation measurements performed thus far using portable analysers or other simple indicator devices, they may constitute a reliable basis for assessment of the process quality. These measurements, although not as accurate as laboratory tests, are sufficient for making alterations at the production stage of the respiratory agent. Limited access to appropriate diagnostic tools has led in many cases to erroneous decisions being made as to the condition of the process under monitoring. The implementation of simple[20], but relatively expensive indicators of filter cartridge consumption levels has hitherto not provided the required precision.

Until recently, due to the lack of adequate measuring and safety systems, this situation promoted the uninformed[21] operation of a faulty production system. Detection of a faulty process was not possible until periodic testing[22] or optional[23] checking of the quality of the breathing agent by the operator. The proposed method of performing online operational measurement allows to identify the real capacity of the processes of obtaining, maintaining, and distributing breathing air. The main distinguishing feature of this type of monitoring is its reliable and useful capability to detect standardised breathing gas pollutants in combination with the implementation of appropriate warning systems. By focusing the measurement on the assessment of key input and process parameters, potential technical and/or physiological hazards to hyperbaric systems and divers can be prevented at the production stage.

WORK OBJECTIVE

The aim of this study is to evaluate the effectiveness of performing online and offline control of selected critical CTQ parameters of the respiratory air filtration process. The evaluation of the mentioned control methods should allow confirmation as to their potential use in assessing the current state of the capability of the rationalised process. Its rationalisation should be understood as the reduction of the number of CO_2 defects[23] in the process of obtaining breathing air for hyperbaric oxygen conditions from the level 10%(2,78σ) to < 5%(3,14σ).

MATERIAL AND METHODS

The evaluation of the process capability to control carbon dioxide content was performed for the compressed air supply system of the DGKN - 120 complex at KTPP AMW – Fig.1 and 2. The data review and analysis of process variability over time was conducted using the SixSigma approach, based on recognised scientific methods, which is one of many pro-quality systems. This method was used to seek deterministic disturbances of the process, allowing to diagnose how far it deviates from its natural variability.

According to DMAIC[25,26] once a process has been defined[27] its current state must be determined. After a benchmarking analysis of available[28] measurement systems, for economic and production reasons[29], it was decided to develop an in-house, multidimensional measurement system for online control of the CCS process[30]. The validation of the system, taking into account the current legal and normative conditions, was carried out by means of tests of metrological quality characteristics and an evaluation of the capability to perform measurements in a hyperbaric environment[31]. The qualification and analysis of the measurement system for process supervision has already been described [14] and will not be reviewed in this paper. System evaluation was conducted using MSA procedures[32] and SPC statistical process control methods[33].

Fig.1-2 Configuration of the breathing air supply and treatment equipment of the $DGKN-120$ complex. Source: own study.

During the definition phase, a detailed process map was developed (Fig. 3). Compressed air was subjected to multi-stage purification in a dehumidifier and a filter set. Monitoring of CO_2 content was carried out at the input and output of the process. The developed measurement system was equipped with an alarm indicator[34] signalling the exceeding of the established process specification limits $(USL; LSL)$[35].

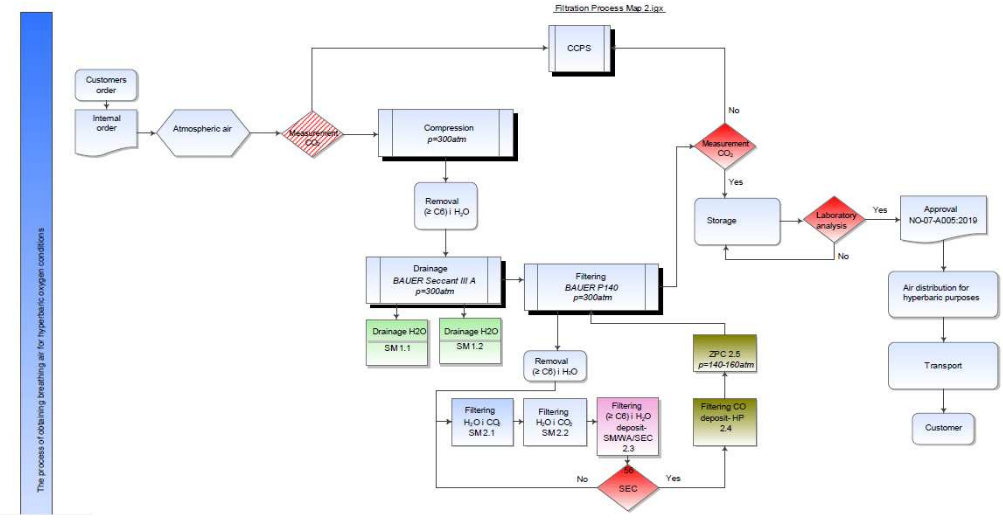


Fig. 3 Process map. Source: own study.

Taking into account the assumed reduction of the number of defects, in terms of the defined customer VOC requirements[36], critical quality requirements CTQ were identified, defined and prioritised, understood among others as the CO_2 content at the output of the compression system content at the output of the compression and filtration system and the filter bed breakthrough time[37]. The process defect was unambiguously defined, the Y_{1-2}[38] metrics were established, and the process objectives and specification limits were set for individual defined CTQs in accordance with the applied rules[39] – tab.1. hence, a data collection plan was developed for the selected CTQs, operational definitions were established, and initial process parameters were determined from $x_1 - x_7$, the measurement system was selected, sample size, sampling method and frequency were estimated – tab.2.

Tab. 1

CTQ operational definitions for the process of obtaining breathing air. Source: own study.

Defining and CTQ ranking

CTQ	*Measure Y*	*Defect description*	*Objective*	*Specification limit* [LSL − USL]	*Permissible defect level* Share
Y_1	100% adjustment of C_{CO_2} in controls ample to $NO-07-A005{:}2010$, $STANAG$ 1458 requirements during compression and filtration system operation. Indicators $C_p, C_{pk} \geq 1$	$C_{CO_2} \geq 500[ppm]$ during compression and filtration system operation. Indicators $C_p, C_{pk} < 1$	$C_{CO_2} \leq 500[ppm]$	$C_{CO_2} \leq 500[ppm]$	5%
Y_2	Defect-free operation time of the compression and filtration system understood as the filter bed breakthrough time	$t_p \leq 50\ hours$ $t_p \leq 3msc.$	$t_p \geq 3msc.$ $t_p \geq 50\ hours$	$t_p \geq 3msc.$ $t_p \in 50 \div 100\ hours$	10%
Y_3	Number of defects of measuring system/accuracy and precision assured	Variability of measuring system $GRR \geq 30$ $\leq 2{,}8\sigma$ in time t< 5 $msc.$	[≥4σ] Y_{FT} =99,4%	[≥3σ] Y_{FT} =93,3%	[≥2,8σ] Y_{FT} =90,3%

Tab. 2

Data collection plan for the process of obtaining breathing air. Source: own study.

Data collection plan

CTQ	*Symbol*	
measure Y	Y_1	Y_2
measure type	At the process output downstream of the breathing air filtration system. Key process measurement for the product	At process outlet. Time t_p of defect-free operation of the breathing air filtration system
data type	Continuous data	Continuous data
operational definition	Carbon dioxide content (concentration) $C_{CO_2} \leq 500ppm$ in the control sample of compressed breathing air, measured under normobaric conditions	Time from compressor activation during which carbon dioxide value in the control sample of compressed breathing air after the filtration set does not exceed $C_{CO_2} \leq 500ppm$
measurement procedure	Automated online measurement performed at the production station	Automated online measurement performer at the production station
system	CCS, Carbon Dioxide Control System Vaisala CARBOCAP@Carbon Dioxide Module $GMM112$ validated system, calibration in time t< 5msc	
measurement system	[1ppm±1]	[h./min]
measurement unit	Automatic recording of CO_2 content every: 1, 2 or 10 s of compression and filtration system operation	Automatic recording of CO_2 content every:1, 2 or 10 s of compression and filtration system operation
sampling rate	*Online* measurements of the compression and filtration system operation – minimum: $[60/min]$	Online measurements of the compression and filtration system operation $min.$: $[60/min]$
$X = x_1..x_i$	$x_1 - C_{CO_2\ a}\,[ppm]$ – carbon dioxide CO_2 concentration in atmospheric air at the compression inlet $x_2 - T_a[C^0]$ – temperature of the atmospheric air at the compressor inlet $x_3 - T_z[C^0]$ – temperature of the atmospheric air of the filter system bed $x_4 - RH[\%]$ – relative humidity of the atmospheric air at the compressor inlet x_5 –operator $x_6 - m_s$ – filter bed filling configuration $x_7 - t_{pr}$ – operation time	$x_1 - C_{CO_2\ a}\,[ppm]$ – concentration of carbon dioxide CO_2 in the atmospheric air at the compressor inlet $x_2 - T_a[C^0]$ –temperature of the atmospheric air at the compressor inlet $x_3 - T_z[C^0]$ – temperature of the atmospheric air of the filter system bed $x_4 - RH[\%]$ –relative humidity of the atmospheric air at the compressor inlet x_5 –operator $x_6 - m_s$ – filter bed filling configuration $x_7 - t_{pr}$ – operation time

A data collection plan involving non-simultaneous, single-element control sampling at a specified sampling rate was adopted for implementation. Data were collected in a database for further inference. As a target, the use of data sheets was envisaged to monitor the process and to assess its stability [15]. This will allow monitoring of the process and identification of its potential deviations, thus enabling prediction of the occurrence of hazards. The methods for developing and selecting cards for rationalising a given process will not be mentioned here, as they have already been described in sufficient detail [16,17,18]. The capability of the production process will be determined by its capability indicators.

This will be regulated, i.e. stable, centred and under control, if the critical quality requirements $CTQ\ Y_1 = C_{CO_2} \leq 500[ppm]$ and $Y_2 = t_p \geq 3msc$ are met. The current state of available technology, which can be used to obtain significant quantities of air suitable for hyperbaric oxygen conditions, does not allow the establishment of higher critical CTQ requirements for process capability. As indicated by the FMEA risk analysis matrix[40], only the application of threshold analytical indicators causing an increase in detection from incomplete $98\% > D_{\%} \geq 90\%$ to ideal $D_{\%} \cong 100\%$ causes a decrease in the relative numerical probability of detection from D = 9 to D = 1.

This entails a decrease in the value of the relative risk number to the acceptable level of RPN = 72 (9). Using a reliable CCS measurement system for process control, empirical data of carbon dioxide content collected from daily operation of the compression and filtration system were analysed. The data obtained with the qualified system were the basis for assessing the capability and stability of the analysed process. Guided by the criterion of best and worst case, two distributions of measurement data series were selected.

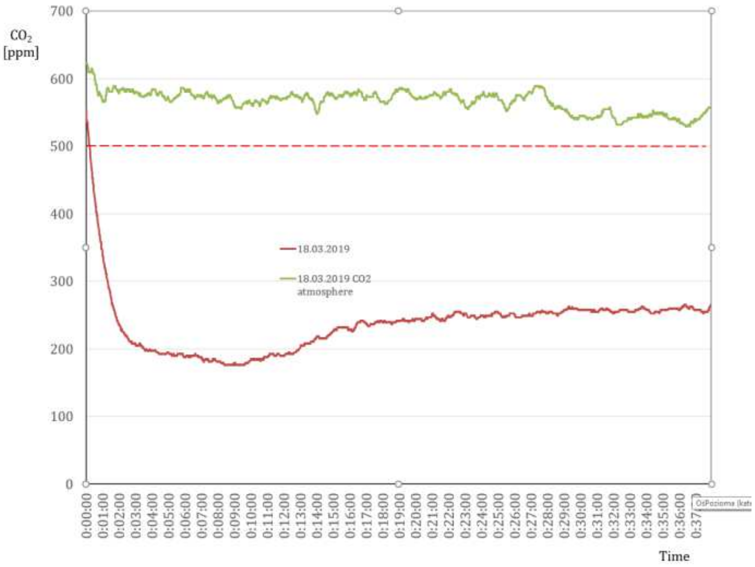


Fig. 2 Distribution of empirical process data for ($n \gg 30, \mathrm{LSL} = 0,\ USL = 500\,ppm$) following replacement of $C_{CO_2} > USL$ filter media on 18.03.2019. Source: own study.

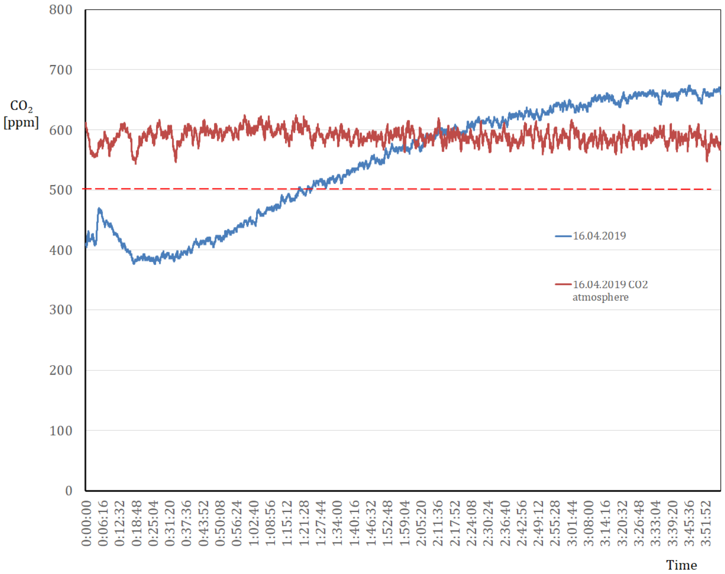


Fig. 3 Distribution of empirical process data for ($n \gg 30, \mathrm{LSL} = 0,\ USL = 500\,ppm$) following the first breakthrough of $C_{CO_2} > USL$ filter media on 16.04.2019. Source: own study.

One of them, which is a relative reference distribution, was obtained immediately after replacing the filter cartridge with a new one after the first start-up of the filtration system, fig. 2. The comparative distribution was the data obtained on the day of exceeding the established tolerance limit of the process at the time τ≈20min after starting the compression and filtration system, fig. 3.

In both cases C_{CO_2} content was observed in the atmosphere of compression system inlet[41], which for reference distribution was $\bar{x}_{co_2 1} = 571ppm$, $Me = 558ppm$ fig. 2 and for comparative distribution $\bar{x}_{co_2 2} = 589ppm, Me = 589ppm$ respectively, fig. 3.

In both cases exceedance of input normalised content of C_{CO_2} in atmospheric air was identified, because $\bar{x}_{co_2 1}, \bar{x}_{co_2 2} > C_{CO_2}^{max} = 500ppm$.

Particular observations[42] were confirmed for each distribution during the analysed period of operation fig. 4. The analysis indicates that exceedances of the normalised concentration limit of C_{CO_2} in atmospheric air are of permanent character. In industrialised areas, this is not surprising as an increasing C_{CO_2} content in the atmospheric air has been observed for years[43]. Similar phenomena of increased local concentration have been observed in the absence of proper ventilation of production halls, uncontrolled emissions of pollutants and/or exhaust gases in the vicinity of the intake of compression systems.

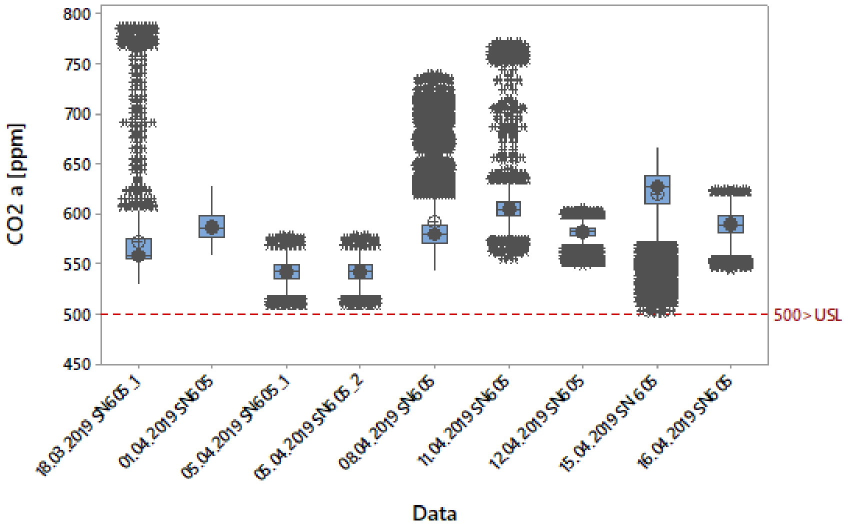
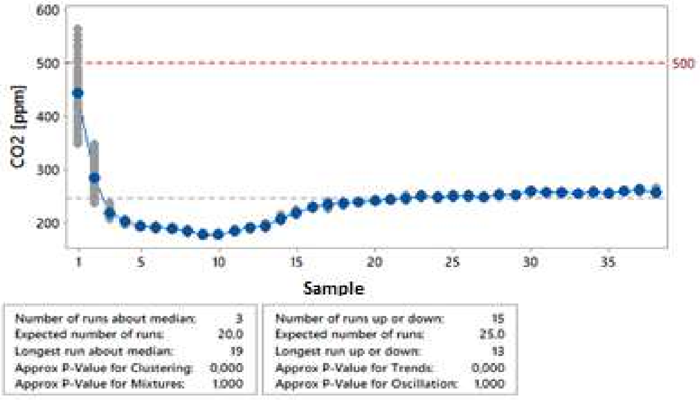


Fig. 4 The variability of CO_2 content in the atmosphere of the air intake during the analysed period of production of breathing air. Source: own study.

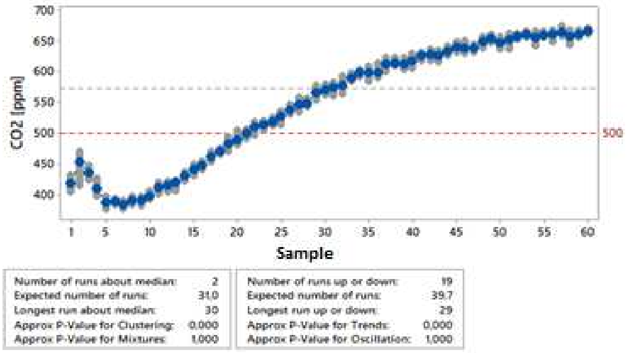
The obtained distributions were plotted on so-called run charts, Fig. 5-6, where the significance of clusters and trends was demonstrated on the basis of the performed tests[44].



Number of runs about median:	3
Expected number of runs:	20.0
Longest run about median:	19
Approx P-Value for Clustering:	0,000
Approx P-Value for Mixtures:	1,000

Number of runs up or down:	15
Expected number of runs:	25.0
Longest run up or down:	13
Approx P-Value for Trends:	0,000
Approx P-Value for Oscillation:	1,000

Fig. 5 Run-chart for breathing air samples after filter set following filter cartridge replacement on 18.03.2019 with control lines plotted for Me and USL. Source: own study.



Number of runs about median:	2
Expected number of runs:	31,0
Longest run about median:	30
Approx P-Value for Clustering:	0,000
Approx P-Value for Mixtures:	1,000

Number of runs up or down:	19
Expected number of runs:	39.7
Longest run up or down:	29
Approx P-Value for Trends:	0,000
Approx P-Value for Oscillation:	1,000

Fig. 6 Run-chart for breathing air samples after filter set on the date of breakthrough of the filter, i.e. on 16.04.2019 with control lines plotted for Me and USL. Source: own study.

The obtained measurement data are presented in the histograms in Fig.7 and 8. In contrast to the reference distribution, this allowed the identification for $Y_1 = C_{CO_2} \leq 500[ppm]$ of approximately 65,5% $(1{,}11\sigma)$ of the occurring process defects in the critical comparative distribution Fig. 8.

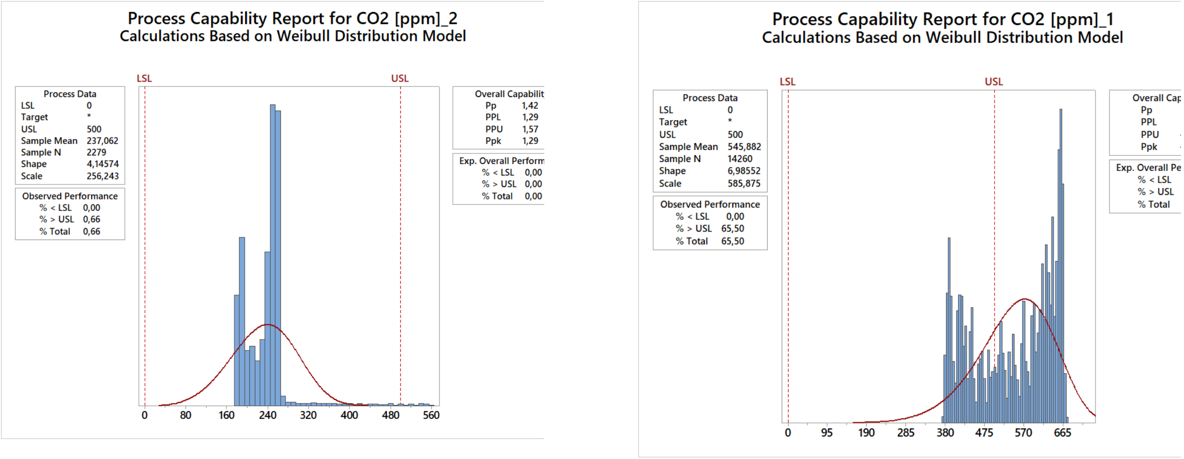


Fig. 7–8 Analysis of process capability based on distributions obtained after replacement and breakthrough of filter cartridges in days $(18.03.2019\ v.\ 16.04.2019)$. Source: own study.

The evaluation of the process in the two defined states, in accordance with the assumption made, is described by the corresponding process capability indicators C_p; C_{pk} and/or P_p; P_{pk}[45]. The reference distribution can be considered as capable but unstable in time. Exceedances of the USL specification limit during the start-up phase of the compression and filtration system, cause $0{,}66\%(3{,}98\sigma)$ of the process defects, which corresponds to: $P_p, P_{pk} = [1{,}42; 1{,}29]min > 1$ – fig. 7.

Accordingly, the comparative distribution reveals as much as 65,5% defects, where: P_p, $P_{pk} = [0{,}93; -0{,}26]min < 1$ – fig. 8.

This leads to confirmation of the conclusion that the modern redundant filtration systems[46] used do not have sufficient resistance (solidity)[47] to changes in environmental parameters. For these reasons it will be necessary to carry out an in-depth process risk assessment at the analysis stage[48]. This will allow identification of special factors[49] and verification of their influence on the process response.

In order to confirm the observations obtained, further inference was carried out based on a larger sample consisting of $n = 62$ consecutive distributions of historical data, which were plotted on the histogram – fig. 9.

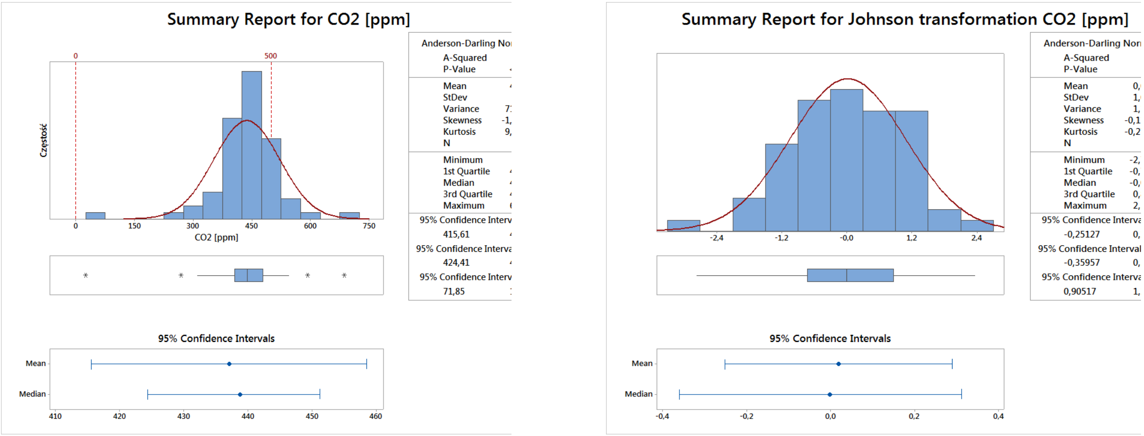


Fig. 9–10 Adjustment of data set $Y_1 = \bar{x}_{CO_2}$ to distribution and transformation of distribution $\bar{x}_{CO_2}$ using the Johnson method. The distribution of data before and after transformation with near normal distribution with $p - value = 0{,}902 > 0{,}05$, $AD = 0{,}19$. Source: own study.

After adjusting the distribution, the data were transformed to obtain the distribution constituting the basis for fig. 10 to evaluate the process capability for the critical requirement $Y_1 = C_{CO_2} \leq 500[ppm]$. The analysis of the time-distributed measurement data series indicated, using an automated online detection system, the occurrence of $17{,}74\%(2{,}43\sigma)$ of product defects on average in the sample, thus confirming the lack of capability– fig. 11 and process stability over time – fig. 12. Consequently, 17,74% of identified process defects for $n = 62$ distributions correspond to: C_p, $C_{pk} = [0{,}86, 0{,}51]min < 1$ and values $P_p, P_{pk} = [0{,}63; 037]min < 1$.

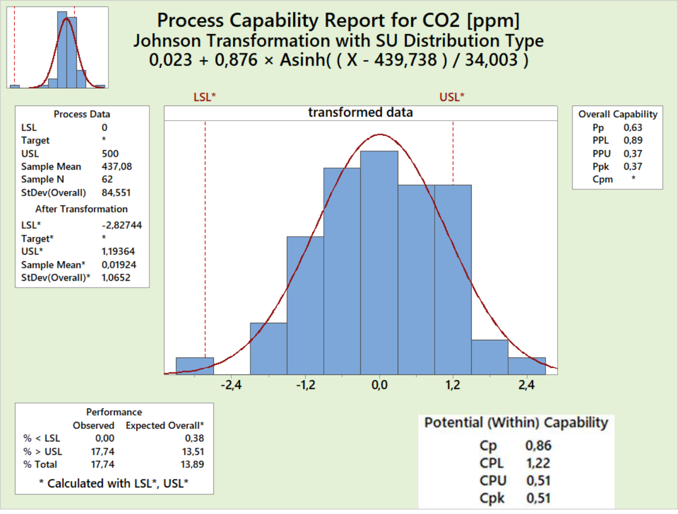


Fig. 11 Preliminary analysis of capability of the process for obtaining breathing air for hyperbaric oxygen conditions for $Y_1 = \bar{x}_{CO_2}$ and $n = 62$ observation series in terms of elimination of CO_2 pollutants following data transformation using the Johnson method. Source: own study.

The obtained data were plotted on a developed control chart of mean values and spread $\bar{x} - R$ fig. 12. On the chart of $\bar{x}$ mean values, points appear which are outside the established control lines LCL[50] and UCL[51]. The occurring trends indicate a periodic shift of the process and its change in position and scatter with respect to the central line. The process is unstable, uncentred and not under statistical control and the influences of deterministic factors cause excessive variability[52].

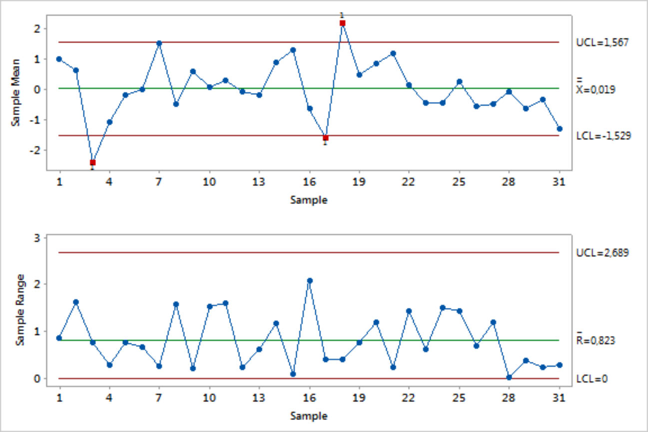


Fig. 12 Control chart $X - R$ for the data distribution for $Y_1 = \bar{x}_{CO_2}$ and $n = 62$ observation series for CO_2 pollutant elimination after Johnson data transformation for $n = 2$. Source: own study.

Based on the historical distributions, the filter breakthrough time for the next quality requirement $CTQ,\ Y_2 = t_p \geq 3msc$ and/or $50 hours$ was evaluated. The results obtained were surprising. It was found that in no case the time of protective operation approached the lower limit of the specification. In 100% of cases the process was outside the limit of the established tolerance.

The primary breakthrough occurred after $t_p = 1170min$ of operation after replacing the filter cartridge with a new one, i.e. approximately $t_p = 19,5\ hours < Y_2. = 50\ hours$ – fig. 13. The secondary breakthrough[53] occurred on average after approximately $\bar{t} = 102\ min$ of operation, from each subsequent start-up. After elimination of the outlier measurement, the data against the established tolerance interval are presented on the histogram of the distribution of the secondary breakthrough time Y_2 of the filtration bed for $n = 28$ series of measurements –fig. 14.

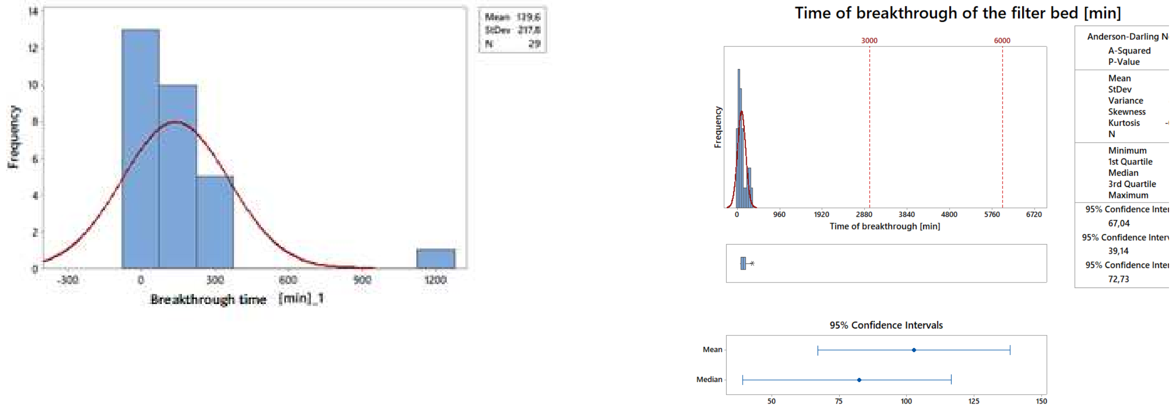
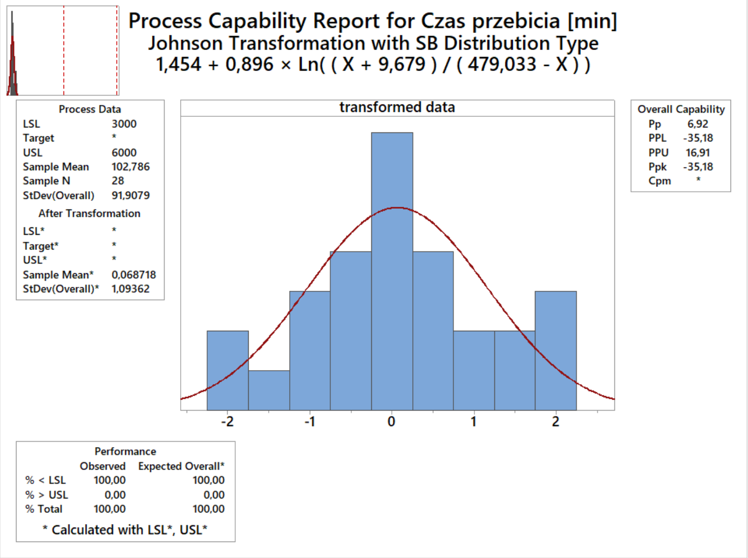


Fig.13 –14 Histogram of the distribution of the primary and secondary breakthrough times Y_2 of the filter bed for $n = 28$ series of measurements against the background of a fixed process tolerance interval $(LSL = 50\ hours,\ USL = 100\ hours)$. Source: own study.

After transformation of the obtained distribution, the data were plotted in fig. 15, which indicates the process capability with respect to the breakthrough time $t_p = Y_2$ of the filter bed for $C_{CO_2} \geq 0,05\%_v$ and $n = 28$ series of measurements against the tolerance interval. The process is outside the specification range $P_p = 6,92,\ P_{pk} = -35,18 \ll 1$[54]. To fulfil the critical quality requirements CTQ the actual ratios should be high $C_p, C_{pk} \geq 1$[55]. The significant discrepancy of P_p, P_{pk} values indicates the potential for process improvement after correction and shifting its position relative to the specification limits.


Process Capability Report for Czas przebicia [min]
Johnson Transformation with SB Distribution Type
1,454 + 0,896 × Ln((X + 9,679) / (479,033 - X))

Process Data

LSL	3000
Target	*
USL	6000
Sample Mean	102,786
Sample N	28
StDev(Overall)	91,9079

After Transformation

LSL*	*
Target*	*
USL*	*
Sample Mean*	0,068718
StDev(Overall)*	1,09362

Overall Capability

Pp	6,92
PPL	-35,18
PPU	16,91
Ppk	-35,18
Cpm	*

Performance

	Observed	Expected Overall*
% < LSL	100,00	100,00
% > USL	0,00	0,00
% Total	100,00	100,00

* Calculated with LSL*, USL*

Fig. 15 Process capability analysis with respect to breakthrough time $C_{CO_2} \geq 0,05\%_v$ of the filtration bed $t_{pr} = Y_2$ for $n = 28$ measurement series against the tolerance interval $(LSL = 50\ hours,\ USL = 100\ hours)$ .Source: own study.

In the case in question, the aim should be to identify the factors that cause the CTQ requirements to be exceeded and the process to move towards $LSL = 50\ hours$, $USL = 100\ hours$.

Consequently, this will allow the development of an improvement plan, its implementation and rationalisation of the process and regain control and the capability expected by the user. In summary, the identified capacity of the process before correction is presented in tab. 3.

Tab. 3

Tabular summary of the assessment of the production process capability prior to rationalisation carried out in the measurement phase.

Constituent	CTQ	Objective	Measurement	Conclusions
Process capability	$Y_1 = C_{CO_2} \leq 500[ppm]$	$5\% > USL$ $C_p\ , C_{pk} \geq 1$	$17{,}74\% > USL$ $C_p, C_{pk} \cong min[\,0{,}86; 0{,}51]$ $P_p, P_{pk} \cong min[0{,}63; 0{,}37]$	Incapable and unstable process ($n = 62$)
	$Y_1' = C_{CO_2} \leq 500[ppm]$	$5\% > USL$ $C_p\ , C_{pk} \geq 1$	$0{,}66\% > USL$ $P_p, P_{pk} \cong min[1{,}42; 1{,}29]$	Process meets CTQ requirement for reference distribution ($n = 1$)
	$Y_2 - t_p \geq 3msc.$ $t_p \geq 50\ hours$	$10\% < LSL$	$100\% < USL$	Incapable and unstable process exceeds tolerance limits ($n = 28$)

The cumulative number of non-conformities at the control measurements of the normalised carbon dioxide pollutants in hyperbaric air at the process output Y_1 for $n = 62$ distributions, significantly exceeds the adopted assumptions and CTQ requirement, i.e. the share of defects at the level of $C_{CO_2} < 5\%$. Such a state requires the implementation of reasonable corrective actions after identification and compensation of causes of process disturbances and evaluation of controlled parameters $(x_1 \dots x_7)$ tab. 2 in order to achieve the minimum objective function understood as:

- Y_1 normalized carbon dioxide content within the tolerance limits $C_{CO_2} \in [0 \div 500]ppm$, where $\exists_{x_1 .. x_i} C_{CO_2} \leq C_{CO_2}^{max}$ where $f \rightarrow min = 0$
- Y_2 perceived as meeting the requirement for the protective time of the system set and filtration $t_p \in [50 \div 100]hours$.

In the analysis of the results of the current process capability assessment, tab. 3, it seems difficult or even impossible to achieve the CTQ requirements without technology modification. The answer as to the scale of corrective actions taken and/or modification of the current technology may be known after carrying out research[56] allowing to identify the influence of parameters[57] on the process response or factors interacting with them.

CONCLUSIONS

The use of qualified, reliable and useful systems with proven effectiveness allows for full control of the production process of a respiratory agent. Implementation of new measuring systems[58] should be preceded by verification tests[59] in terms of meeting the declared metrological parameters [19]. Comparison of the results of process capability assessments obtained with automated measurement systems, with the distributions of historical data of laboratory tests in 2018÷2019, indicates the advantages of their application.

In the analysed sample of laboratory tests for controlled normalised carbon dioxide content, only $C_{CO_2} \geq 500ppm = Y_1 \approx 10\% = C_{CO_2\,offline}$ process defects for class II according to NO-07-A005:2020 were revealed to occur. Similarly, the automated system revealed the presence of $Y_1 \approx 17{,}74\% = C_{CO_2\,online}$[60] process defects.

Accordingly, using the existing laboratory control system, no $\Delta = Y_1 = C_{CO_2\,online} - C_{CO_2\,offline} = 17{,}74 - 10 = 7{,}74\%$ defects were found and identified during the in-service testing.

The current best, under the operating conditions for the test facility analysed, has not allowed a higher than $2{,}43\sigma$ process capability. It appears that achieving a target of $> 3{,}14\sigma$ is feasible. This leads to the conclusion that the obligatory data collection plan required to date, consisting of taking a non-simultaneous, one-element control sample from each operating power source every three months or after 50 hours of operation, is insufficient. This monitoring method does not allow full control and process regulation, often leading to incorrect assessment and inference about the current status of the compression and filtration systems [20]. The process variability observed during the study indicates that in the case of continuous operation of the compression system in $t \in (2 - 6)\ hours$, the sampling frequency should adopt an interval not longer than a few minutes. The use of traditional periodic laboratory control does not reflect the real state of the process.

In order to observe and control the process on an ongoing basis, the best solution is to implement underestimated and relatively low-cost[61], automated indicative control systems, while maintaining overriding laboratory control. Paradoxically, advanced methods of laboratory qualitative and quantitative analysis[62] despite high precision and correctness of measurements, do not ensure the possibility of appropriate reaction to dynamic changes in the state of the process. Such a method of control, due to the high cost of laboratory analyses, low frequency of tests and their limited availability[63], is insufficient.

The process is unstable and incapable, and the observed scale of the lack of resistance of the filtration systems to the process disturbances occurring is surprising. The time of protective operation of the bed until the first breakthrough did not meet the CTQ requirements and amounted to $Y_2 < 50\,hours$. It can be intuitively concluded that this is caused, among others, by the observed high content of contaminants in the atmosphere of the compression system intake of $C_{CO_2} > 500ppm$[64]. Identification of key causes of exceeding the CTQ requirements process hazards will be further investigated[65]. Due to the extent of the problem, elimination of failures to meet CTQ requirements will not be possible without modification of the currently used technology[66] for the elimination of carbon dioxide[67]. Regaining process control and minimising the proportion of CO_2 defects will lead to an increase in the level of safety of underwater operations while reducing the cost of poor quality[68].

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[1] Department of Underwater Works Technology of the Polish Naval Academy,
[2] experimental deep-water hyperbaric system,
[3] NATO - North Atlantic Treaty Organization,
[4] §11.5 and §11.6 Chapter 3,
[5] SOP – standard of procedures,
[6] such as $poka - yoke$,
[7] e.g. $SCADA$ – $Supervisory\ Control\ and\ Data\ Acquisition$,
[8] e.g. capable of measuring the contents of: CO_2, CO, VOC, H_2O, O_2, etc. according to product specification requirements,
[9] executive elements,
[10] SPC – S$tatistical\ Process\ Control$,
[11] i.e. periodic inspection by the operator based on generally available simple measurement systems,
[12] CTQ – $Critical\ to\ Quality$,
[13] $offline$,
[14] used, *inter alia*, for experimental research on the development and implementation of new diving technologies,
[15] GLP – $Good\ Laboratory\ Practice$,
[16] in a military or civilian environment, as appropriate,
[17] not adapted to the requirements of the supervised process,
[18] test results obtained from the physico-chemical laboratory $WTM\ 1\ RBlog$,
[19] resulting from internal and external costs of poor quality,
[20] e.g. $SECURUS$,
[21] producing process defects,

[22] usually neglected by the user or unreliable,
[23] subject to error,
[24] revealed in laboratory control,
[25] *Define, Measure, Analyse, Improve, Control*,
[26] with the optimisation of existing processes,
[27] the following were defined: purpose, scope, rationale, team and customer needs and requirements, critical requirements were identified and ranked,
[28] such as the measurement set *ACG Analox*, *DIVEAIR 2 Geotechnical Instruments* (UK) Ltd etc.,
[29] available measurement systems did not meet the requirements of the process and the VOC user target expectations revealed during the KANO analysis phase. In fact, a positive quality was generated in the product and rationalised process by developing an in-house CCS control system,
[30] *CCS – Carbon Dioxide Control System,*
[31] control sample decompressed to normobaric conditions,
[32] *Measurement System Analysis,*
[33] *Statistical Process Control,*
[34] visual and acoustic,
[35] *LSL* – Lower Specification Limit; *USL* – Upper Specification Limit,
[36] VOC – *Voice of client,*
[37] loss of capability of the filtration system to purify ambient air within the specification limits,
[38] Y_3 was analysed at the stage of validation of the measurement system CCS. Process measurement results are satisfactory if they are maintained at the level of at least $\geq 3\sigma$, which corresponds to ≥ 93,3%,
[39] *SMART – Specific*, *Measurable*, *Achievable*, *Relevant* (from the point of view of the client), *Trackable* (possibility to track result levels),
[40] the detailed results of the process FMEA risk analysis performed will not be reported here,
[41] measurement at process inlet,
[42] of reference and comparative distributions,
[43] continuously observed and confirmed by *Mauna LOA Observatory* in Hawaii at the (*NOAA*)*National Oceanic and Atmospheric Administration* laboratory collecting measurements of CO_2 content in ambient air since 1974. The average content of $\bar{\mathrm{x}}_{\mathrm{co_2}} = 413{,}54\mathrm{ppm}$ was recorded in April 2019,
[44] resulting in a consequent loss of control over the process,
[45] short and long term position and spread of the process,
[46] excessive,
[47] *Robust Design,*
[48] at the next stage in the implementation of the methodology resulting from the Six Sigma approach,
[49] leading to a loss in process capability,
[50] *LCL* – Lower Control Limit,
[51] *UCL*- ang. Upper Control Limit,
[52] not revealed yet,
[53] occurring during subsequent compressor start-ups after the initial “breakthrough” of the bed after a time t_p,
[54] long-term volatility takes into account all causes of volatility. It is therefore a good indicator of the real process capability,
[55] in processes, it is recommended that, whenever possible, the value of the index is $C_{pk} > 1{,}33$. In companies for which product quality is a priority, the value of the capability indexes is assumed to be at least $C_p, C_{pk} > 1{,}67$,
[56] e.g. using methods: *DOE*, *Mixture Design* ,*Taguchi*, etc.,
[57] controlled and uncontrolled,
[58] indicator systems,
[59] e.g. as part of laboratory and in-service testing of individual pieces of equipment,
[60] the identified process capability limit for a single distribution was as high as Y_1 =65%$(\,1{,}1\,\sigma)$ of the identified product defects,
[61] as compared e.g. with the external costs of low quality of the product,
[62] using gas chromatography with mass spectrometry,
[63] currently, in the civilian environment, the problem of availability of laboratory tests has not been solved. In contrast to the intensive work in the military area, the civilian environment, despite the applicable normative requirements arising from the provisions of PN-W-88503:1998 and EU: PN EN 12021:2014-08 have not taken systemic measures to establish proper control and specialist supervision,
[64] the adequacy of the choice of the filtration system is appropriate to the limits of the carbon dioxide content of the ambient air at $\mathrm{C}_{\mathrm{CO_2}a} = 0 \div 500\mathrm{ppm}$,
[65] the significance of the influence of the analysed parameters on the response of the process should be revealed at subsequent stages of the work,
[66] e.g. using the DFSS – *Design for Six Sigma* – approach. A method of designing a new product and/or process, or redesigning an existing one if the process has reached its capability limit,
[67] process capability indicators: $P_p = 6{,}92$, $P_{pk} = -35{,}18 \gg 1{,}33$,
[68] internal and external,