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Dräger safety

October 27, 2003

Nima Ashkeboussi
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Ashkeboussi:

This letter is in reference to the NRC's letter dated August 11, 2003, requesting for additional information.

As discussed and agreed through our phone conversation, Draeger Safety is still in the process of applying for the State of Texas possession license. Please review the enclosure during the meantime while we wait to finish the Texas license submission.

Thank you for your assistance, please feel free to contact me at (281) 207-1212 if there are concerns or issues.

Best regards,

Victor Hoang
Senior Engineer
Draeger Safety, Inc.

Enclosure: As stated

Gas Detection Systems
505 Julie Rivers, Suite 150
Sugar Land, TX 77478
Phone: (281) 207-1212
Fax: (281) 498-5190
www.draeger.com

ENCLOSURE

1. ADDITIONAL INFORMATION

1.1. Please refer to attached drawings (attachments A & B) referring to the dimensions of detector unit in Figures 4a and 5a.

1.2. Please refer to the attached table (attachment C) for a comparison to delineate the differences between Models 5000, 5100, 5600, and 5700. (TIC=Toxic Industrial Compounds, AMC=Airborne Molecular Compounds, CWA=Chemical Warfare Agents).

1.3. On very rare occassions, the end-users will require placement of the detector in a hazardous area. Hazardous area is an area where there is a potential of explosive gas present.

The detector would be mounted in a third party explosion proof control enclosure (attachment D). The enclosure is certified to contain any sparks and prevents them from escaping into the outside area. The enclosure would be rated explosion proof for Class I, Groups B, C, and D.

1.4. The IMS unit is a stand alone detector, personnel exposure is vey limited and only during maintenance. With this fact in mind, we will assume exposure time of no more than 2,000 hour in a year.

a) Referring to Attachment II (PTB) from the original application, the dosage time of the IMS device is less than 10 μSv / hour = 20 mSv / year = 2 rem / year = 0.001 rem. (10 mSv = 1 rem). This value meets the dose limit requirements as required by 10 CFR 32.27(a) and 32.28.
b) A quality check on each device assures that the dose rate must be less than 0.1 μSv / hour = 0.2 mSv / year = 0.02 rem /year = 0.00001 rem
Activity per area (Bq / cm^2) = 0.0001 Bq / cm^2

1.5. A copy of the point of sale label is enclosed (attachment E)

1.6. The IMS is manufactured by Draeger Safety in Germany and shipped to Draeger Safety in Texas for sales and distribution. Quality assurance steps are performed in Germany and in the U.S. according to ISO 9001 procedures. Enclosed are copies of the Quality Assurance manuals from Draeger Safety Germany and Draeger Safety U.S. (Attachments F & G)

1.7. Please refer to the attached picture for the location of the label affixed to the device corresponding to Figure 4a. (Attachment H).

1.8. The IMS is strictly used in a fixed system configuration. It is mounted in a rack, therefore it would be unlikely that the detector would be subjected to a free fall as tested. The test was performed based on a worst case scenario of accidental drop. Please refer to section 2.1 on construction details and design of the device.

1.9. We are currently applying for a possession license with the State of Texas.

1.10. There are no byproduct materials generated from the IMS, just standard ions from pure air and there are no chemical filters. The filter is strictly for moisture and dust retention.

2. CLARIFICATIONS

2.1. The detector unit is housed in a polypropylene enclosure with heavy walls of 8 mm thickness. The radioactive source is tightly mounted at one end of the cylindrical IMS cell.

The sealed source (detector unit) is enclosed in a 19" rack mountable enclosure which is packed in a foam box during transport.

The source itself is protected by a silicon dioxide protective layer to prevent abrasion.

2.2. Confirm, the limiting condition for the operation of the device should be the operating temperature range(0 C to 50 C).

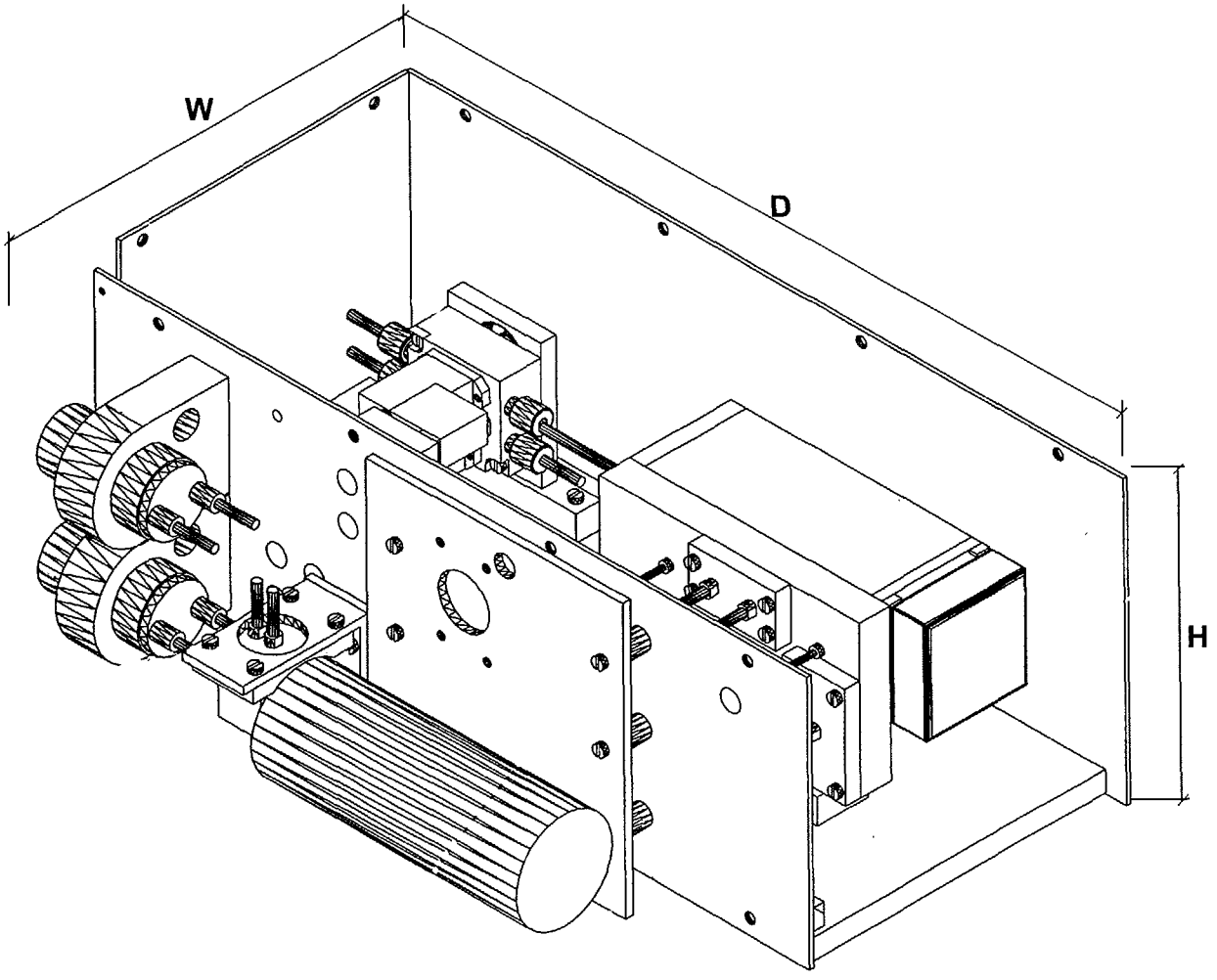
2.3. Each IMS unit contains one source, its maximum activity is 1 MBq.

2.4. There is no contact potential between aluminum and steel or any other unlike materials in and on the sealed source in the Draeger IMS, therefore no contact corrosion.

2.5. The IMS is used in semiconductor plants and analytical labs for monitoring toxic substances such as ammonia, chlorine, hydrogen chloride, hydrogen fluoride. Theses substances are harmful to humans and also to properties (e.g. integrated ciruits contaminants, equipment corrosions).

2.6. Even if the filter is not changed within the six months window, the level of tritium build-up would not exceed 1 GBq, which is still under the free limit (Germany).

ATTACH A

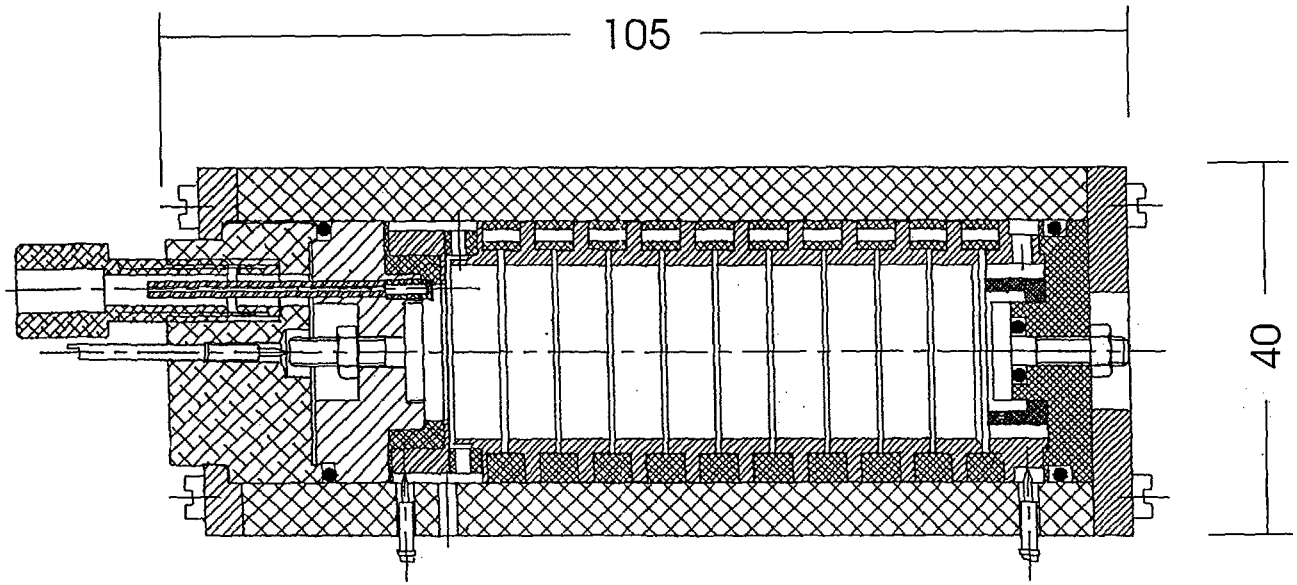


W x H x D = 190 x 105 x 290 mm

Darstellung mit geöffnetem Thermokasten

				Maße ohne Toleranzangabe nach DIN 7168 mittel		Stückzahl	Maßstab
							Werkstoff / Halbzeug
					Datum	Name	Benennung
				Bearb	20.11.00	Unger	Einschub
				Gepr.			
				Norm			
				Freig.			
				Dräger SAFETY			Zeichng.-Nr. 12.000-02-00:00 (3)
Zust.	Änderung	Datum	Name				Blatt / Bl.

ATTACH B

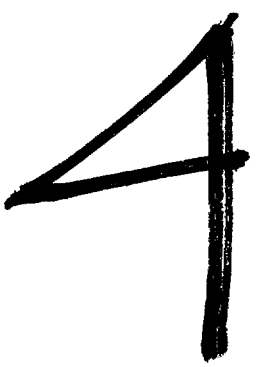


W x H x D = 105 x 40 x 38 mm

				Maße ohne Toleranzangabe nach DIN 7168 mittel		Stückzahl	Maßstab 2 : 1
							Werkstoff / Halbzeug
				2000	Datum	Name	Benennung
				Bearb.	11.10.00	Dr.Eckert	
				Gepr.	15.10.00	STEP Zimm.	Beta–Drift röhre
				Norm			
				Freig.	17.10.00	Dr. Schü/Hop	
				J.U.T./STEP			Zeichng.–Nr. RID5.50–02:00
Zust.	Änderung	Datum	Name				Blatt Bl.

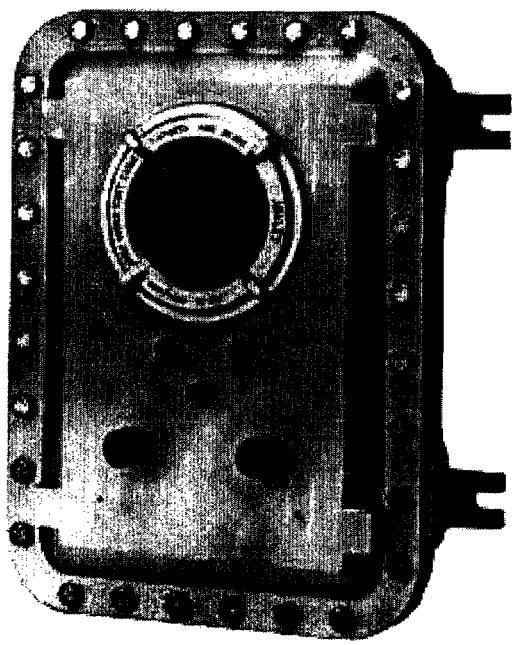
	IMS 5000	IMS 5100	IMS 5600	IMS 5700
Detectable Compounds	TIC, AMC	TIC, AMC, CWA	TIC, AMC	TIC, AMC, CWA
Weight / kg	9	9	10	10
No of pumps	2	2	3	3
No of filters	1	1	2	2
GC column	no	no	yes	yes
Software		Incl. CWA	Incl. Capability to evaluate 3 dimensional spectra	Incl. CWA Incl. Capability to evaluate 3 dimensional spectra

ATTACH C



ATTACH D

XCE EXPLOSIONPROOF CONTROL ENCLOSURES
XJF EXPLOSIONPROOF JUNCTION BOXES FLANGED



Applications:

Adalet XCE series and XJF enclosures are used in the installation of electrical/electronic components for control, measurement or monitoring applications in hazardous environments. XCE control enclosures can be modified for installation of a variety of explosionproof operator devices, viewing windows and accessories permitting the development of customized enclosure systems.

Features

- Copper-free aluminum, lightweight and corrosion resistant.
- Integral, cast-on mounting lugs, slotted for ease of field installation.
- Uniform wall thickness for ease of installation of control devices, windows and conduit openings.
- External flange provides maximum accessibility of components mounted inside.
- Tumblast finish for quality appearance.
- Premium high strength steel cover bolts, plated and coated for maximum corrosion resistance (stainless steel optional).
- Enclosures certified drillable for conduit entrances in the factory or the field.
- Internal grounding screw standard.
- Covers exceeding approximately 75 lbs. are provided with two removable eye bolts for ease of handling.
- XCE/XCEQ/XCEX certified drillable for operators at the factory or in the field.
- IP40 standard on XCEX without gasket.

Design Options

- CENELEC flameproof optional – designate XCEX when ordering. Includes external earthing assembly.
- Quad-lead bolt (quick thread bolt) option - designate XCEQ when ordering. Not available with XCEX.
- NEMA 4 (WATERTIGHT)/IP66:
  Features a nitrile O-Ring retained in the cover flange in a machined groove. When ordering, add N4 to the catalog number. *This option may affect certifications - consult factory.
- NEMA 6 (SUBMERSIBLE):
  Consult factory.
- Cast-on mounting buttons, bosses and pads:
  Per customer specifications.
- Captive cover bolts:
  Consult factory.
- Hinges:
  May be installed for removable or non-removable cover. Left side standard, other locations optional.
- Windows:
  Circular window sizes ranging from 1" to 8" diameter viewing area. Rectangular window sizes ranging from 3" x 3" to 13" x 13" viewing area.
- Stainless steel cover bolts. Consult factory for NEMA 4X rating.
- Mounting Pans:
  Available in galvanized steel, aluminum or phenolic.
- Sidewall auxiliary device installation or machining available on XCE/XCEQ/XCEX series enclosures – Consult Factory.
- Factory machined metric sidewall threads approved on XCE and XCEX series for Groups C & D only.
- The Adalet engineering department is available to assist in the selection of custom explosionproof enclosures for your products.

Certifications

XCE Series Control Enclosures

UL STANDARD 1203
CSA STANDARD C22.2 No. 30

EN 50 018 (XCEX)

XJF Junction Boxes

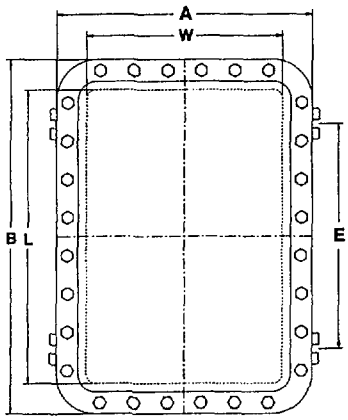
CSA STANDARD C22.2 No. 30

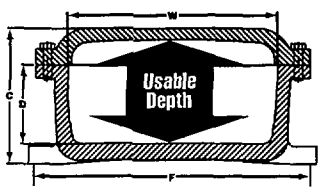
UL STANDARD 886

Class I, Groups B,C,D
Class II, Groups E,F,G
Class III
CENELEC: EExd IIB, (Specify XCEX)
ATEX Certifications available – Consult Factory.
NEMA 4, 7B*CD, 9EFG

Some sizes and option combinations may not be certified.
Consult Factory for specific certifications and file numbers.

XCE & XJF Explosionproof Enclosures





- To indicate Quad-Lead bolt option, add suffix "Q" after XCE. (Not available on XCEX models.)
- Operators, windows and hinges are ordered separately.
- To indicate EEx d approval specify XCEX.
- To indicate NEMA 4/IP66 option, add suffix "N4" after size (catalog number).

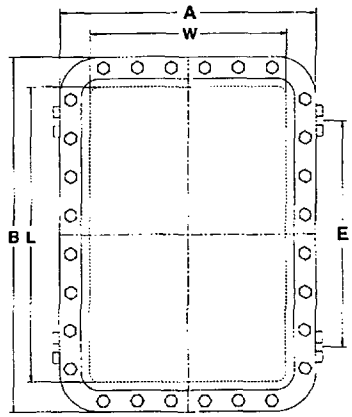
Note: All dimensions are in inches and are nominal enclosure size only. Inside nominal dimensions are at flange. Consult factory for exact dimensions.

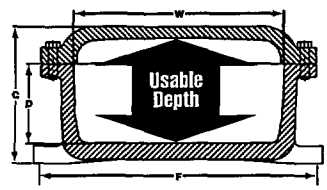
*Approval Pending – Consult Factory.

XCE/XJF Catalog Number	Inside Nominal Dimensions W	L	D	Usable Inside Depth	Overall Dimension A	B	C	Mounting Lug CL to CL E	F	Mtg. Bolt Size	Approx. Shipping Weight, lbs.
041604	4	16	4	4 3/4	7 1/4	19 1/4	6	12 1/8	6 3/4	3/8	25
060804	6	8	4	4 5/8	9 1/4	11 1/4	5 15/16	4 1/2	9 1/8	3/8	21
060805	6	8	5	5 5/8	9 1/4	11 1/4	6 15/16	4 1/2	9 1/8	3/8	23
060806	6	8	6	6 5/8	9 1/4	11 1/4	7 15/16	4 1/2	9 1/8	3/8	25
061105	6	11	5	5 7/8	9 1/4	14 1/4	7 3/16	7 1/2	9 1/8	3/8	24
061204	6	12	4	4 3/4	9 1/4	15 1/4	6 1/16	8 1/2	9 1/8	3/8	24
061206	6	12	6	6 3/4	9 1/4	15 1/4	8 1/16	8 1/2	9 1/8	3/8	29
061305	6	13	5	5 7/8	9 1/4	16 1/4	7 3/16	9 1/2	9 1/8	3/8	26
071004	7	10	4	4 3/4	10 3/8	13 3/8	6 3/16	6 1/2	9 3/4	3/8	27
071006	7	10	6 1/8	6 3/4	10 3/8	13 3/8	8 3/16	6 1/2	9 3/4	3/8	31
071805	7	18 1/4	5	5 3/4	10 3/8	21 5/8	7 3/16	14 1/2	9 3/4	3/8	55
080804	8	8	4	4 13/16	11 3/8	11 3/8	6 3/8	4 1/4	11	3/8	24
080806	8	8	6	6 13/16	11 3/8	11 3/8	8 3/8	4 1/4	11	3/8	28
080808	8	8	8	8 13/16	11 3/8	11 3/8	10 3/8	4 1/4	11	3/8	35
081004	8	10	4	4 3/4	11 3/8	13 3/8	6 1/4	6 1/2	10 3/4	3/8	30
081006	8	10	6	6 3/4	11 3/8	13 3/8	8 1/4	6 1/2	10 3/4	3/8	34
081008	8	10	8	8 3/4	11 3/8	13 3/8	10 1/4	6 1/2	10 3/4	3/8	39
081204	8	12	4	4 3/4	11 3/8	15 3/8	6 1/4	8 1/2	10 3/4	3/8	34
081206	8	12	6	6 3/4	11 3/8	15 3/8	8 1/4	8 1/2	10 3/4	3/8	42
081208	8	12	8	8 3/4	11 3/8	15 3/8	10 1/4	8 1/2	10 3/4	3/8	48
091105	9	11	5	5 3/4	12 3/8	14 3/8	7 5/16	7 1/2	12	3/8	41
101004	10	10	4	4 3/4	13 3/8	13 3/8	6 5/16	6 1/2	13	3/8	34
101006	10	10	6	6 3/4	13 3/8	13 3/8	8 5/16	6 1/2	13	3/8	44
101008	10	10	8	8 3/4	13 3/8	13 3/8	10 5/16	6 1/2	13	3/8	50
101206	10	12	6 1/4	7 1/4	13 3/8	15 3/8	8 7/8	8 1/2	13 1/4	3/8	46
101404	10	14	4	4 3/4	13 3/8	17 3/8	6 7/16	10 5/8	13 1/4	3/8	42
101406	10	14	6	6 3/4	13 3/8	17 3/8	8 7/16	10 5/8	13	3/8	49
101408	10	14	8	8 3/4	13 3/8	17 3/8	10 1/2	10 5/8	13	3/8	57
* 101410	10	14	8	10 13/16	13 3/8	17 3/8	12 7/16	10 5/8	13	3/8	70
121204	12	12	4	5	16 1/4	16 1/4	6 15/16	8 5/8	15 3/4	1/2	60
121206	12	12	6	7	16 1/4	16 1/4	8 15/16	8 5/8	15 3/4	1/2	68
121208	12	12	8	9	16 1/4	16 1/4	10 15/16	8 5/8	15 3/4	1/2	80
121804	12	18	4	4 3/4	16 1/4	22 1/4	6 3/4	14 1/8	15 3/4	1/2	85
121806	12	18	6	6 3/4	16 1/4	22 1/4	8 3/4	14 1/8	15 3/4	1/2	93
121808	12	18	8	8 3/4	16 1/4	22 1/4	10 3/4	14 1/8	15 3/4	1/2	101
122005	12	20	5	5 3/4	16 1/4	24 1/4	8 1/8	14 3/8	15 3/4	1/2	104
122404	12	24	4	4 15/16	16 1/4	28 1/4	7 1/4	18 3/8	15 3/4	1/2	116
122406	12	24	6	6 15/16	16 1/4	28 1/4	9 1/4	18 3/8	15 3/4	1/2	127

XCE & XJF Explosionproof Enclosures

	XCE/XJF Catalog Number	Inside Nominal Dimensions W	L	D	Usable Inside Depth	Overall Dimension A	B	C	Mounting Lug CL to CL E	F	Mtg. Bolt Size	Approx. Shipping Weight, lbs.
	122408	12	24	8	8 15/16	16 1/4	28 1/4	11 1/4	18 3/8	15 3/4	1/2	140
	122410	12	24	10	10 15/16	16 1/4	28 1/4	13 1/4	18 3/8	15 3/4	1/2	154
	123006	12	30	6	6 11/16	16 3/4	34 1/4	9 5/8	23	15 3/4	1/2	180
	123604	12	36	4	4 15/16	16 1/4	40 1/4	7 11/16	29	15 3/4	1/2	192
	123606	12	36	6	6 15/16	16 1/4	40 1/4	9 11/16	29	15 3/4	1/2	212
	123608	12	36	8	8 15/16	16 1/4	40 1/4	11 11/16	29	15 3/4	1/2	232
	124608	12	46	8	8 15/16	16 1/4	50 1/4	11 11/16	39	15 3/4	5/8	280
	141404	14	14	4	5	18 1/4	18 1/4	7 1/8	9 3/4	17 3/4	1/2	91
	141406	14	14	6	7	18 1/4	18 1/4	9 1/4	9 3/4	17 3/4	1/2	97
	141408	14	14	8	9	18 1/4	18 1/4	11 1/8	9 3/4	17 3/4	1/2	103
*	142210	14	22	10	11 1/4	18 1/4	26 1/4	13 5/8	16 1/2	17 3/4	1/2	181
*	142213	14	22	10	13	18 1/4	26 1/4	15 1/8	16 1/2	17 3/4	1/2	235
	142806	14	28	6	7 13/16	18 1/4	32 1/4	9 9/16	22 1/2	17 3/4	1/2	120
	161604	16	16	4	6 5/8	20 7/8	20 7/8	7 15/16	11	19 3/4	5/8	114
	161606	16	16	6	7 5/8	20 7/8	20 7/8	9 15/16	11	19 3/4	5/8	135
	161608	16	16	8	9 5/8	20 7/8	20 7/8	11 15/16	11	19 3/4	5/8	156
	162406	16	24	6	7 13/16	20 7/8	28 7/8	10 3/8	18 3/8	19 3/4	5/8	190
	162408	16	24	8	9 13/16	20 7/8	28 7/8	12 3/8	18 5/8	19 3/4	5/8	209
	162410	16	24	10	11 13/16	20 7/8	28 7/8	14 3/8	18 3/8	19 3/4	5/8	225
	162806	16	28	6	6 13/16	20 1/2	32 11/16	9 1/2	22 1/2	19 3/4	5/8	200
	163406	16	34	6	6 15/16	20 1/2	38 1/2	9 1/2	27	19 3/4	5/8	260
	163010	16	30	10	11 1/8	20 1/2	34 1/2	13 7/8	27	19 3/4	5/8	320
	164610	16	46	10	11 13/16	20 7/8	50 7/8	14 9/16	39	19 3/4	5/8	390
	181804	18	18	4	5 13/16	22 7/8	22 7/8	8 1/2	13	21 3/4	5/8	154
	181806	18	18	6	7 13/16	22 7/8	22 7/8	10 1/2	13	21 3/4	5/8	177
	181808	18	18	8	9 13/16	22 7/8	22 7/8	12 1/2	13	21 3/4	5/8	200
	182406	18	24	6	7 7/16	22 7/8	28 7/8	10 13/16	18 3/8	21 3/4	5/8	226
	182408	18	24	8	9 7/16	22 7/8	28 7/8	12 13/16	18 3/8	21 3/4	5/8	239
	182410	18	24	10	11 7/16	22 7/8	28 7/8	14 13/16	18 3/8	21 3/4	5/8	260
	183008	18	30	8	9 3/8	22 7/8	34 7/8	12 13/16	23	21 3/4	5/8	293
	183608	18	36	8	9 3/8	22 7/8	40 7/8	12 7/8	29	21 3/4	5/8	318
	183610	18	36	10	11 3/8	22 7/8	40 7/8	14 7/8	29	21 3/4	5/8	340
*	203606	20	36	6	7 1/8	24 7/8	40 7/8	10 7/8	29	24	5/8	340
*	203612	20	36	6	12	25 5/8	41 5/8	15	29	24	5/8	415
*	204806	20	48	6	7 1/8	24 7/8	52 7/8	10 7/8	41	24	5/8	430
*	204812	20	48	6	12	25 5/8	53 5/8	15	41	24	5/8	515
	242408	24	24	8	9 7/16	28 7/8	28 7/8	12 7/16	18 3/8	28	5/8	302
	242410	24	24	10	11 7/16	28 7/8	28 7/8	14 7/16	18 3/8	28	5/8	330
	243008	24	30	8	9 1/4	28 7/8	34 7/8	12 15/16	23	28	5/8	356
	243608	24	36	8	9 1/4	28 7/8	40 7/8	12 7/16	29	28	5/8	408
	243610	24	36	10	11 1/4	28 7/8	40 7/8	14 7/8	29	28	5/8	433
*	243612	24	36	10	12	28 7/8	40 7/8	16 1/2	29	28	5/8	545
*	323612	32	36	6	12	37 3/4	41 3/4	15 1/2	29	36 1/8	5/8	691





- To indicate Quad-Lead bolt option, add suffix "Q" after XCE. (Not available on XCEX models.)
- Operators, windows and hinges are ordered separately.
- To indicate EEx d approval specify XCEX.
- To indicate NEMA 4/IP66 option, add suffix "N4" after size (catalog number).

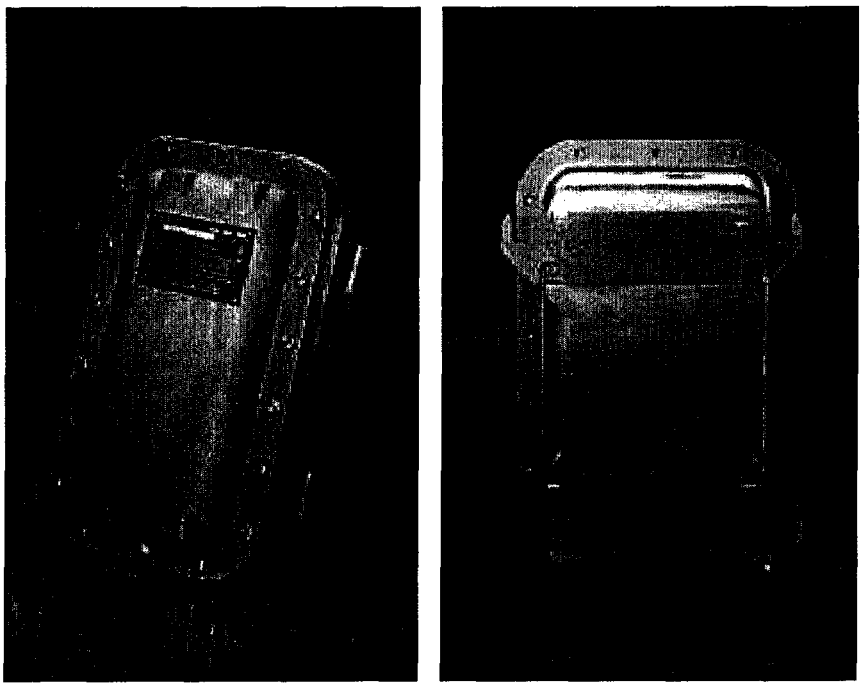
Note: All dimensions are in inches and are nominal enclosure size only. Inside nominal dimensions are at flange. Consult factory for exact dimensions.

*Approval Pending – Consult Factory.

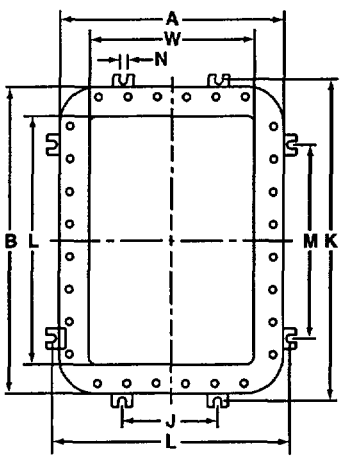
5A–3

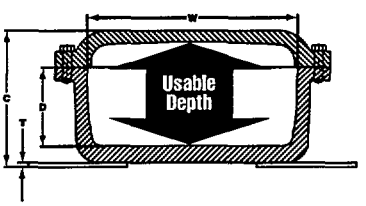
Bolt-On Mounting Lugs for XCE & XJF Enclosures

Adjust To Irregular Mounting Surfaces Without Damaging Enclosures



Adalet Bolt-On Mounting Lugs for XCE and XJF Enclosures are bi-directional, permitting either vertical or horizontal mounting orientation. The ductile aluminum alloy lugs adapt to irregular surfaces so lug bolts can be tightened without damaging the enclosure.





Bolt-On Mounting Lugs

Catalog Number	Mounting Dimensions Optional Mounting J	K	Standard Mounting L	M	Mtg. Lug Size N	Mtg. Lug Thickness T
XCE060804M	X	X	7 7/8	4	3/8	1/4
XCE060805M	X	X	7 7/8	4	3/8	1/4
XCE060806M	X	X	7 7/8	4	3/8	1/4
XCE061105M	X	X	7 7/8	9	3/8	1/4
XCE061204M	X	X	7 7/8	10	3/8	1/4
XCE061206M	X	X	7 7/8	10	3/8	1/4
XCE061305M	X	X	7 7/8	11	3/8	1/4
XCE071004M	X	X	8 7/8	8	3/8	1/4
XCE071006M	X	X	8 7/8	8	3/8	1/4
XCE071805M	X	X	8 7/8	16	3/8	1/4
XCE080804M	X	X	9 7/8	6	3/8	1/4
XCE080806M	X	X	9 7/8	6	3/8	1/4
XCE080808M	X	X	9 7/8	6	3/8	1/4
XCE081004M	X	X	9 7/8	8	3/8	1/4
XCE081006M	X	X	9 7/8	8	3/8	1/4
XCE081008M	X	X	9 7/8	8	3/8	1/4
XCE081204M	3 13/16	14 3/8	10 3/8	7 13/16	1/2	3/8
XCE081206M	3 13/16	14 3/8	10 3/8	7 13/16	1/2	3/8
XCE081208M	3 13/16	14 3/8	10 3/8	7 13/16	1/2	3/8
XCE091105M	4 13/16	13 3/8	11 3/8	9	1/2	3/8
XCE101004M	5	13	13	5	1/2	3/8
XCE101006M	5	13	13	5	1/2	3/8
XCE101008M	5	13	13	5	1/2	3/8
XCE101206M	5	15	13	6	1/2	3/8
XCE101404M	5	17	13	9	1/2	3/8
XCE101406M	5	17	13	9	1/2	3/8
XCE101408M	5	17	13	9	1/2	3/8
XCE101410M	5	17	13	9	1/2	3/8
XCE121204M	7	15	15	7	1/2	3/8
XCE121206M	7	15	15	7	1/2	3/8
XCE121208M	7	15	15	7	1/2	3/8
XCE121804M	7	20 7/8	15	12 7/8	1/2	3/8
XCE121806M	7	20 7/8	15	12 7/8	1/2	3/8
XCE121808M	7	20 7/8	15	12 7/8	1/2	3/8
XCE122005M	7	22 7/8	15	14 7/8	1/2	3/8
XCE122404M	7	26 7/8	15	18 7/8	1/2	3/8
XCE122406M	7	26 7/8	15	18 7/8	1/2	3/8
XCE122408M	7	26 7/8	15	18 7/8	1/2	3/8
XCE122410M	7	26 7/8	15	18 7/8	1/2	3/8
XCE123006M	7	33	15	24 7/8	1/2	3/8
XCE123604M	7	39	15	31	1/2	3/8
XCE123606M	7	39	15	31	1/2	3/8
XCE123608M	7	39	15	31	1/2	3/8

Catalog Number	Mounting Dimensions Optional Mounting J	K	Standard Mounting L	M	Mtg. Lug Size N	Mtg. Lug Thickness T
XCE124608M	7	49	15	41	1/2	3/8
XCE141404M	9	17	17	9	1/2	3/8
XCE141406M	9	17	17	9	1/2	3/8
XCE141408M	9	17	17	9	1/2	3/8
XCE142806M	9	31	17	23	1/2	3/8
XCE161604M	11	19	19	10 15/16	1/2	3/8
XCE161606M	11	19	19	10 15/16	1/2	3/8
XCE161608M	11	19	19	10 15/16	1/2	3/8
XCE162406M	11 3/8	27 1/4	19 3/8	19 3/8	1/2	3/8
XCE162408M	11 3/8	27 1/4	19 3/8	19 3/8	1/2	3/8
XCE162410M	11 3/8	27 1/4	19 3/8	19 3/8	1/2	3/8
XCE162806M	11 3/8	31 3/8	19 3/8	23	1/2	3/8
XCE163406M	11 3/8	37 3/8	19 3/8	29 3/8	1/2	3/8
XCE164610M	11 3/8	49 3/8	19 3/8	41 3/8	1/2	3/8
XCE181804M	13 3/8	21 3/8	21 3/8	13 3/8	1/2	3/8
XCE181806M	13 3/8	21 3/8	21 3/8	13 3/8	1/2	3/8
XCE181808M	13 3/8	21 3/8	21 3/8	13 3/8	1/2	3/8
XCE182406M	13	27	21	19	1/2	3/8
XCE182408M	13	27	21	19	1/2	3/8
XCE182410M	13	27	21 1/4	19	1/2	3/8
XCE183008M	13	31	21	25	1/2	3/8
XCE183608M	13 1/4	39 1/2	21	31 1/2	1/2	3/8
XCE183610M	13 1/4	39 1/2	21 1/4	31 1/2	1/2	3/8
XCE203606M	15 3/4	39 3/4	23 3/4	31 3/4	1/2	3/8
XCE204806M	15 3/4	51 3/4	23 3/4	43 3/4	1/2	3/8
XCE242408M	19 1/2	27 1/2	27 1/2	19 1/2	1/2	3/8
XCE242410M	19 1/2	27 1/2	27 1/2	19 1/2	1/2	3/8
XCE243008M	19 9/16	33 9/16	27 9/16	25 9/16	1/2	3/8
XCE243608M	19 9/16	39 9/16	27 9/16	31 9/16	1/2	3/8
XCE243610M	19 9/16	39 9/16	27 9/16	31 9/16	1/2	3/8

XCE Series Recommended Spacing For Operators In Covers

Catalog Number	Standard Operators Maximum Number Operators	Maximum Number Operator Rows	Maximum Number Operators Per Row	Recommended Spacing CL to CL	Miniature Operators Maximum Number Operators	Maximum Number Operator Rows	Maximum Number Operators Per Row	Recommended Spacing CL to CL	Cover Wall Thickness (Inches)
XCE041604	5	5	1	2 1/2	13	13	1	1	1/2
XCE060804	2	2	1	2 1/2	8	4	2	1	1/2
XCE060805	2	2	1	2 1/2	8	4	2	1	1/2
XCE060806	2	2	1	2 1/2	8	4	2	1	1/2
XCE061105	3	3	1	2 1/2	14	7	2	1	1/2
XCE061204	4	4	1	2 1/2	16	8	2	1	5/8
XCE061206	4	4	1	2 1/2	16	8	2	1	5/8
XCE061305	4	4	1	2 1-2	18	9	2	1	1/2
XCE071004	6	3	2	2 1/2	18	6	3	1	5/8
XCE071006	6	3	2	2 1/2	18	6	3	1	5/8
XCE071805	12	6	2	2 1/2	45	15	3	1	5/8
XCE080804	4	2	2	2 1/2	16	4	4	1	11/16
XCE080806	4	2	2	2 1/2	16	4	4	1	11/16
XCE080808	4	2	2	2 1/2	16	4	4	1	11/16
XCE081004	6	3	2	2 1/2	24	6	4	1	11/16
XCE081006	6	3	2	2 1/2	24	6	4	1	11/16
XCE081008	6	3	2	2 1/2	24	6	4	1	11/16
XCE081204	8	4	2	2 1/2	32	8	4	1	11/16
XCE081206	8	4	2	2 1/2	32	8	4	1	11/16
XCE081208	8	4	2	2 1/2	32	8	4	1	11/16
XCE091105	6	3	2	2 1/2	35	7	5	1	11/16
XCE101004	9	3	3	2 1/2	36	6	6	1	11/16
XCE101006	9	3	3	2 1/2	36	6	6	1	11/16
XCE101008	9	3	3	2 1/2	36	6	6	1	11/16
XCE101206	12	4	3	2 1/2	48	8	6	1	3/4
XCE101404	12	4	3	2 1/2	60	10	6	1	3/4
XCE101406	12	4	3	2 1/2	60	10	6	1	3/4
XCE101408	12	4	3	2 1/2	60	10	6	1	3/4
XCE101410	12	4	3	2 1/2	60	10	6	1	3/4
XCE121204	9	3	3	3	64	8	8	1	7/8
XCE121206	9	3	3	3	64	8	8	1	7/8
XCE121208	9	3	3	3	64	8	8	1	7/8
XCE121804	15	5	3	3	92	14	8	1	15/16
XCE121806	15	5	3	3	92	14	8	1	15/16
XCE121808	15	5	3	3	92	14	8	1	15/16
XCE122005	18	6	3	3	128	16	8	1	1 1/8
XCE122404	21	7	3	3	150	20	8	1	1 1/8
XCE122406	21	7	3	3	150	20	8	1	1 1/8
XCE122408	21	7	3	3	150	20	8	1	1 1/8

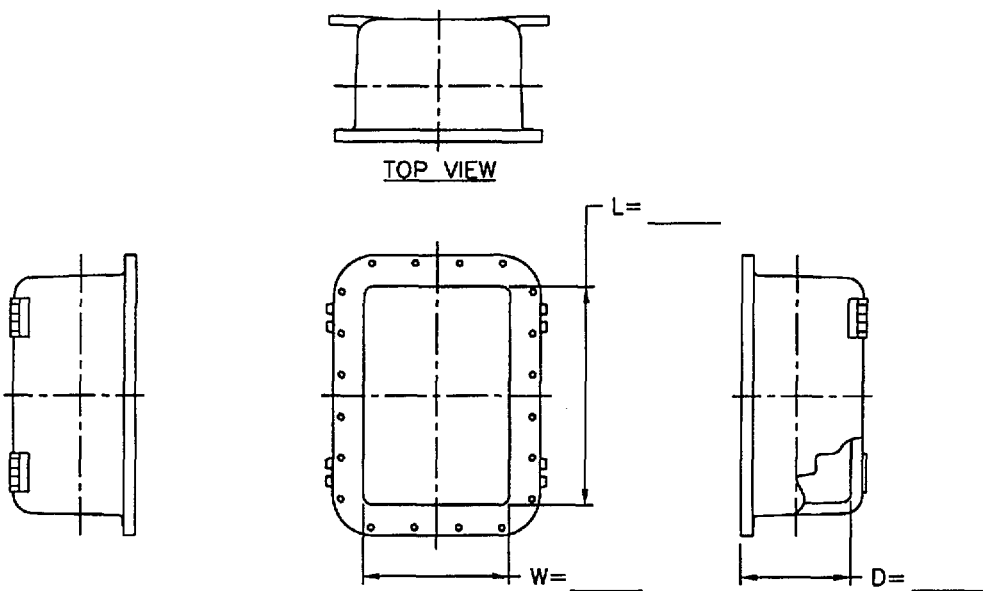
Note: Closer spacing other than 2½ & 3 inches available – Consult factory for special designs.

XCE Series Recommended Spacing For Operators In Covers

Catalog Number	Standard Operators				Miniature Operators				Cover Wall Thickness (Inches)
	Maximum Number Operators	Maximum Number Operator Rows	Maximum Number Operators Per Row	Recommended Spacing CL to CL	Maximum Number Operators	Maximum Number Operator Rows	Maximum Number Operators Per Row	Recommended Spacing CL to CL	
XCE122410	21	7	3	3	150	20	8	1	1 1/8
XCE123006	27	9	3	3	150	26	8	1	1 3/8
XCE123604	33	11	3	3	150	32	8	1	1 3/16
XCE123606	33	11	3	3	150	32	8	1	1 3/16
XCE123608	33	11	3	3	150	32	8	1	1 3/16
XCE124608	42	14	3	3	150	41	8	1	1 1/4
XCE141404	16	4	4	3	100	10	10	1	7/8
XCE141406	16	4	4	3	100	10	10	1	7/8
XCE141408	16	4	4	3	100	10	10	1	7/8
XCE142210	24	6	4	3	100	18	10	1	1 1/8
XCE142213	24	6	4	3	100	18	10	1	1 1/8
XCE142806	32	8	4	3	150	24	10	1	1 1/8
XCE161604	16	4	4	3 1/2	121	11	11	1	7/8
XCE161606	16	4	4	3 1/2	121	11	11	1	7/8
XCE161608	16	4	4	3 1/2	121	11	11	1	7/8
XCE162406	24	6	4	3 1/2	150	19	11	1	7/8
XCE162408	24	6	4	3 1/2	150	19	11	1	7/8
XCE162410	24	6	4	3 1/2	150	19	11	1	7/8
XCE162806	28	7	4	3 1/2	150	24	11	1	1 1/4
XCE163010	32	8	4	3 1/2	150	26	12	1	1 1/4
XCE163406	32	8	4	3 1/2	150	30	11	1	1 1/4
XCE164610	48	12	4	3 1/2	150	41	11	1	1
XCE181804	16	4	4	3 1/2	150	13	13	1	1
XCE181806	16	4	4	3 1/2	150	13	13	1	1
XCE181808	16	4	4	3 1/2	150	13	13	1	1
XCE182406	24	6	4	3 1/2	150	19	13	1	1 1/2
XCE182408	24	6	4	3 1/2	150	19	13	1	1 1/2
XCE182410	24	6	4	3 1/2	150	19	13	1	1 1/2
XCE183008	32	8	4	3 1/2	150	25	13	1	1 1/2
XCE183608	36	9	4	3 1/2	150	31	13	1	1 7/8
XCE183610	36	9	4	3 1/2	150	31	13	1	1 7/8
XCE203606	45	9	5	3 1/2	150	31	15	1	1 7/8
XCE203612	45	9	5	3 1/2	150	31	15	1	1 3/8
XCE204806	65	13	5	3 1/2	150	43	15	1	1 7/8
XCE204812	65	13	5	3 1/2	150	43	15	1	1 3/8
XCE242408	36	6	6	3 1/2	150	19	19	1	1 1/2
XCE242410	36	6	6	3 1/2	150	19	19	1	1 1/2
XCE243008	42	7	6	3 1/2	150	25	19	1	1 7/8
XCE243608	54	9	6	3 1/2	150	31	19	1	1 7/8
XCE243610	54	9	6	3 1/2	150	31	19	1	1 7/8
XCE243612	54	9	6	3 1/2	150	31	19	1	1 3/8
XCE323612	72	9	8	3 1/2	150	31	27	1	1 3/8

Note: Closer spacing other than 3 & 3½ inches available – Consult factory for special designs.

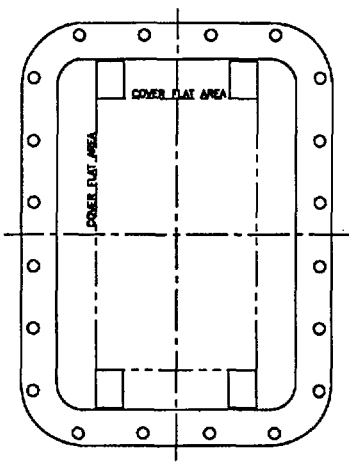
CUSTOMER DESIGN SHEET



BOX LAYOUT

CAT. #: X__ _____

- ☐ N4 O-RING
- ☐ MOUNTING PAN
- ☐ HINGES
  - ☐ LONG SIDE:
    - ☐ LEFT
    - ☐ RIGHT
  - ☐ SHORT SIDE:
    - ☐ TOP
    - ☐ BOTTOM
  - ☐ NON REMOVABLE
- ☐ NO HINGES



COVER LAYOUT

*CONSULT FACTORY FOR FLAT AREA DIMENSIONS

Conduit Drilling and Tapping Guidelines

When drilling & tapping enclosures for conduit, proper installation requires compliance with the following:

1. Must be tapped with at least 5 full NPT threads (XCEX requires six NPT threads) in enclosure back or sides only; min. 1/2" conduit size.
2. Tapping depth of NPT holes must be plus 1/2 turn min. to plus 1-1/2 turns max. past standard NPT plug gage notch.
3. Inner end of conduit openings shall be smooth and well-rounded.

TABLE I

Thread Size Of	Minimum wall thickness at conduit entrance excluding XCEX	
Conduit, Inches (NPT)	Explosionproof	Dust Ignition Proof / Weather Proof
1/2 - 3/4	3/8 inch	1/4 inch
1 - 2	7/16 inch	5/16 inch
2 1/2 - 5	5/8 inch	7/16 inch

TABLE II

Conduit size, inches (NPT)	1/2	3/4	1	1 1/4	1 1/2	2	2 1/2	3	3 1/2	4	5
Minimum Distance from conduit CL to inside corner or back of box	1 5/16	1 7/16	1 9/16	1 3/4	1 7/8	2 1/8	2 3/8	2 11/16	2 15/16	3 1/4	3 7/8
Approximate diameter of union	1 7/8	1 7/8	2 1/16	2 7/8	3 1/4	3 7/8	4 7/8	5 1/2	6	6 1/2	7 1/2

TABLE III

Minimum spacing between conduit centers thru sidewalls only (inches)
(Double all distances in table for holes located in backwall)

Size	5	4	3 1/2	3	2 1/2	2	1 1/2	1 1/4	1	3/4	1/2
1/2	4 1/2	3 5/8	3 3/8	3	2 5/8	2 3/8	2	1 7/8	1 3/4	1 5/8	1 1/2
3/4	4 3/4	3 3/4	3 1/2	3 1/8	2 3/4	2 1/2	2 1/8	2	1 7/8	1 3/4	
1	4 7/8	4	3 5/8	3 1/4	3	2 5/8	2 3/8	2 1/4	2		
1 1/4	5 1/8	4 1/8	3 7/8	3 1/2	3 1/8	2 7/8	2 1/2	2 3/8			
1 1/2	5 1/2	4 1/4	4	3 5/8	3 1/4	3	2 5/8				
2	5 3/4	4 5/8	4 1/4	3 7/8	3 5/8	3 1/4					
2 1/2	6	4 7/8	4 5/8	4 1/4	3 7/8						
3	6 1/4	5 3/8	5	4 5/8							
3 1/2	6 1/2	5 5/8	5 1/4								
4	6 3/4	5 7/8									
5	7 1/4										

This information is compiled from data which we believe is reliable and is given in good faith. Since the methods of application and conditions under which our products are used are beyond our control, we are not able to guarantee the application and/or use of same. The user assumes all risks and liability in connection with the application and use of our products.

Note: All dimensions are in inches.
Metric threads available from factory for Group C & D applications only – Consult Factory.

The Adalet engineering department is available to assist in designing custom explosionproof enclosures for your products.

SPACING FOR AUXILIARY DEVICES INSTALLED IN BOX WALLS OF CONTROL PANEL ENCLOSURES USED IN HAZARDOUS LOCATIONS.

When using an Auxiliary Device in the box wall of an enclosure used in hazardous locations, *proper installation requires compliance with the following:*

1. A minimum of (5) thread engagement, class 2 fit, required for group C & D applications. A minimum of (7) thread engagement, class 2 fit, required for group B applications.
2. *Table I shows minimum box wall thickness for Auxiliary Device threads.*

TABLE I

REQUIRED MINIMUM BOX WALL THICKNESS			
Thread Size (In.)	**Group C & D Applications min. (5) thread engagement**	**Group B Applications min. (7) thread engagement**	**Typical Auxiliary Devices**
1/2 – 3/4 NPSM (14 PITCH)	3/8 Inch	1/2 Inch	XBO, XHPB, XHSS, Standard Operators
1 NPSM (11 1/2 PITCH)	7/16 Inch	5/8 Inch	XCBH Large Handle Assembly
3/8 NPSM (18 PITCH)	*9/32 Inch*	*13/32 Inch*	*XCBH Small Handle Assembly*
3/8 – 16 UNC	5/16 Inch	7/16 Inch	XMOB, XMOSS, Mini Operators

3. If Auxiliary Device contains undercut in engaging threaded section, the minimum wall thickness shown in Table I must increase to maintain the minimum required thread engagement. (Fig. A)
4. Table II provides the minimum distance an Auxiliary Device center can be placed from inside corner or back of box.

TABLE II

AUXILIARY DEVICE THREAD SIZE (In.)	3/8-16 UNC	3/8 NPSM	1/2 NPSM	3/4 NPSM	1 NPSM
Minimum distance from Auxiliary Device CL to inside corner of back of box.	1-1/2	1-5/8	1-3/4	1-7/8	2

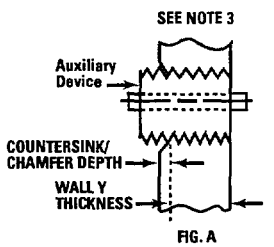


FIG. A

5. Table III shows minimum spacing between conduit and Auxiliary Device entrances.

TABLE III

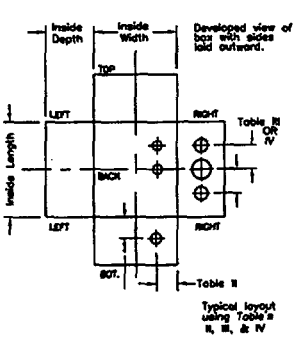
Aux. Device Thread Size	Minimum space between centers of conduits and auxiliary devices in box wall. (Inches) Conduit Thread Size (NPT) 5	4	3-1/2	3	2-1/2	2	1-1/2	1-1/4	1	3/4	1/2
3/8	4-1/2	3-5/8	3-3/8	3	2-5/8	2-3/8	2	1-7/8	1-3/4	1-5/8	1-1/2
1/2	4-5/8	3-3/4	3-1/2	3-1/8	2-3/4	2-1/2	2-1/4	2-1/8	2	1-7/8	1-3/4
3/4	4-3/4	4	3-5/8	3-1/4	2-7/8	2-5/8	2-3/8	2-1/4	2-1/8	2	1-7/8
1	5	4-1/4	3-7/8	3-1/2	3	2-3/4	2-1/2	2-3/8	2-1/4	2-1/8	2

6. Table IV shows minimum spacing between auxiliary device entrances.

   NOTE: Increase distance between devices as required to maintain minimum through air spacing of contacts required by electrical codes.
7. Double all distances in Table III and IV for holes located in back wall.

TABLE IV

Minimum spacing between Auxiliary Device of varying thread sizes (Inches)	3/8	1/2	3/4	1
3/8	1-1/2	1-1/2	1-1/2	2-1/2
1/2	1-1/2	2	2	2-1/2
3/4	1-1/2	2	2	3
1	2-1/2	2-1/2	3	3-1/2



Consult factory for layout data sheets.

XCE and XJF Mounting Pans and Hinges

MOUNTING PANS

Catalog Number (Steel)	Catalog Number (Aluminum)	Catalog Number (Phenolic)	Pan Dimensions Nominal Width	Pan Dimensions Nominal Length	Enclosure Size Reference Inside width x length	Weight Each (pounds) (Steel)
XSM 0416	XSA 0416	XSB 0416	3 1/4	15 1/4	4 x 16	1 1/2
XSM 0608	XSA 0608	XSB 0608	5 1/8	7 1/8	6 x 8	1
XSM 0611	XSA 0611	XSB 0611	5 1/8	10 1/8	6 x 11	1 1/2
XSM 0612	XSA 0612	XSB 0612	5 1/8	11 1/8	6 x 12	1 3/4
XSM 0613	XSA 0613	XSB 0613	5 1/8	12 1/8	6 x 13	2
XSM 0710	XSA 0710	XSB 0710	6 1/8	9 1/8	7 x 10	1 1/4
XSM 0718	XSA 0718	XSB 0718	6 1/8	17 3/8	7 x 18	2 1/2
XSM 0808	XSA 0808	XSB 0808	7	7	8 x 8	1 1/4
XSM 0810	XSA 0810	XSB 0810	7	9 1/8	8 x 10	1 1/2
XSM 0812	XSA 0812	XSB 0812	6 7/8	10 7/8	8 x 12	2 1/4
XSM 0911	XSA 0911	XSB 0911	8	10	9 x 11	2 1/2
XSM 1010	XSA 1010	XSB 1010	8 7/8	8 7/8	10 x 10	2 1/2
XSM 1012	XSA 1012	XSB 1012	10 7/8	8 7/8	10 x 12	3
XSM 1014	XSA 1014	XSB 1014	8 7/8	12 7/8	10 x 14	3 1/2
XSM 1212	XSA 1212	XSB 1212	10 7/8	10 7/8	12 x 12	3 3/4
XSM 1218	XSA 1218	XSB 1218	10 1/2	16 1/2	12 x 18	5 1/2
XSM 1220	XSA 1220	XSB 1220	11	19	12 x 20	6 1/2
XSM 1224	XSA 1224	XSB 1224	11	23	12 x 24	8
XSM 1230	XSA 1230	XSB 1230	10 3/4	28 3/4	12 x 30	9 3/4
XSM 1236	XSA 1236	XSB 1236	10 3/4	34 3/4	12 x 36	11 3/4
XSM 1246	XSA 1246	XSB 1246	10 3/4	44 3/4	12 x 46	15
XSM 1414	XSA 1414	XSB 1414	12 7/8	12 7/8	14 x 14	5
XSM 1422	XSA 1422	XSB 1422	12 7/8	20 7/8	14 x 22	8
XSM 1428	XSA 1428	XSB 1428	12 7/8	26 7/8	14 x 28	10 3/4
XSM 1616	XSA 1616	XSB 1616	14 3/4	14 3/4	16 x 16	6 3/4
XSM 1624	XSA 1624	XSB 1624	14 1/2	22 1/2	16 x 24	10 1/4
XSM 1628	XSA 1628	XSB 1628	26 1/2	14 1/2	16 x 28	12
XSM 1630	XSA 1630	XSB 1630	14 1/2	28 1/2	16 x 30	12 1/2
XSM 1634	XSA 1634	XSB 1634	32 1/2	14 1/2	16 x 34	14 3/4
XSM 1646	XSA 1646	XSB 1646	14 1/2	44 1/2	16 x 46	20 1/4
XSM 1818	XSA 1818	XSB 1818	16 3/4	16 3/4	18 x 18	8 3/4
XSM 1824	XSA 1824	XSB 1824	16 1/2	22 1/2	18 x 24	11 1/2
XSM 1830	XSA 1830	XSB 1830	16 1/2	28 1/2	18 x 30	14 3/4
XSM 1836	XSA 1836	XSB 1836	16 1/2	34 1/2	18 x 36	18
XSM 2036	XSA 2036	XSB 2036	34 1/2	18 1/2	20 x 36	20
XSM 2048	XSA 2048	XSB 2048	46 1/2	18 1/2	20 x 48	27
XSM 2424	XSA 2424	XSB 2424	22	22	24 x 24	15 1/4
XSM 2430	XSA 2430	XSB 2430	22	28	24 x 30	19 1/4
XSM 2436	XSA 2436	XSB 2436	34	22	24 x 36	23 1/2
XSM 3236	XSA 3236	XSB 3236	29	33	32 x 36	28 3/4

HINGES

Hinges Catalog Number	Enclosure Size Reference Inside width x length
XHB-2	4 x 16
XHB-2	6 x 8
XHB-2	6 x 11
XHB-2	6 x 12
XHB-2	6 x 13
XHB-2	7 x 10
XHB-2	7 x 18
XHB-2	8 x 8
XHB-2	8 x10
XHB-2	8 x 12
XHB-2	9 x 11
XHB-2	10 x 10
XHB-2	10 x 12
XHB-2	10 x 14
XHC-2	12 x 12
XHC-2	12 x 18
XHC-2	12 x 20
XHC-2	12 x 24
XHC-2	12 x 30
XHD-3	12 x 36
XHD-4	12 x 46
XHC-2	14 x 14
XHF-2	14 x 22
XHF-2	14 x 28
XHD-2	16 x 16
XHF-2	16 x 24
XHF-2	16 x 28
XHF-2	16 x 30
XHD-3	16 x 34
XHF-4	16 x 46
XHF-2	18 x 18
XHF-2	18 x 24
XHF-2	18 x 30
XHF-3	18 x 36
XHF-3	20 x 36
XHF-4	20 x 48
XHF-2	24 x 24
XHF-2	24 x 30
XHF-3	24 x 36
XHF-3	32 x 36

Mounting Pans

MATERIAL — Steel: (XSM)

Galvanized 12 gauge steel plate. The catalog number includes the steel mounting pan complete with 1/4" high spacers and stainless steel mounting screws.

MATERIAL — Aluminum: (XSA) Consult factory for availability.

MATERIAL — Phenolic: (XSB)

A special phenolic laminated material that has high mechanical and dielectric strength. It is excellent for mounting and wiring control equipment. The catalog number includes the phenolic board, 3/8" thick, complete with 1/4" high spacers and stainless steel mounting screws.

Note: No installation charge when customer specifies factory installation of mounting pan.

Hinge Set

Description:

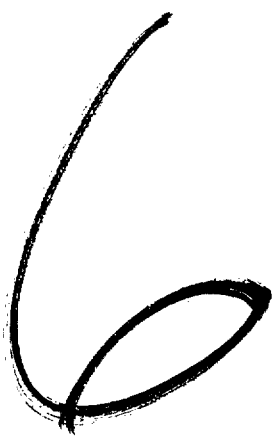
Made of extruded aluminum alloy consisting of two sections, female and male (with stainless steel pin) and four stainless steel hex head bolts. Designed to allow right or left hand removable or non-removable installation.

Unless specified, left hand removable hinge installation will be furnished by factory when hinged enclosures are ordered.

Note: Catalog numbers represent complete hinge sets necessary for enclosure assembly.

THIS DETECTOR CONTAINS
RADIOACTIVE MATERIAL AND HAS BEEN
MANUFACTURED IN COMPLIANCE WITH
U.S. NRC SAFETY CRITERIA IN 10 CFR
32.27. THE PURCHASER IS EXEMPT FROM
ANY REGULATORY REQUIREMENTS.

ATTACH E



ATTACH F

QualitätsManagement - Handbuch
Quality Manual

Dräger
SAFETY

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Lenkung und Änderungshistorie

Das Qualitätsmanagement- Handbuch ist ein gelenktes Dokument.

Aktueller Stand:
Revision
Mai 2002

Ausgabe	Ersatz für	Datum	Beschreibung
Mai 2002	01/2002	03.05.2002	Überarbeitung und Ergänzung Abschnitt 5 „Kommunikation" und „Management Review" Ergänzung der DSTN 0338 in Abschnitt9
Januar 2002	06/2001	01.01.2002	Grundsätzlich, technisch und redaktionell vollständig neu bearbeitet. Die Neuausgabe wurde erforderlich aufgrund der Rezertifizierung nach DIN EN ISO 9001:2000.
06/2001	08/2000	21.06.2001	Austausch KB Verfahren gegen Übersicht "Ablauf Projektmanagement" 06/01 Abschnitt 4
08/2000	12/99	09.10.2000	Austausch Qualitäts- und Umweltpolitik des Dräger Konzerns Stand 07/2000
12/99	09/97	02.12.1999	Reorganisation der Qualitätsabteilung; Business Units übernehmen volle Verantwortung für operative Aufgaben im Qualitätsmanagement.

Control and History of Amendment

The Quality Manual is a controlled Document.

Current Status:
Revision
May 2002

Edition	Replacement for	Date	Description of Changes
May 2002	01/2002	03.05.2002	Revision and supplement of section5 „communication" and „management review" supplement of DSTN 0338 in section9
January 2002	06/2001	01.01.2002	Fully revised, both in technical and editorial terms Recertification according to EN ISO 9001:2000.
06/2001	08/2000	21.06.2001	KB procedure replaced by "Projectmanagement process" 06/01 Section 4.
08/2000	12/99	09.10.2000	Replacement of the Quality and Environmental Policy of the Dräger Group Edition 07/2000.
12/99	09/97	02.12.1999	Reorganization of the Quality Department; Business Units assume full responsibility for operational duties of Quality Management.

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1 Vorwort

Die traditionsreiche Handelsstadt Lübeck - von alters her Knotenpunkt des Handels und der Kultur im Norden Deutschlands - war im ausgehenden 19. Jahrhundert Gründungsstätte des Drägerwerks. Seit dieser Zeit ist die Geschichte der Stadt mit der des Unternehmens verflochten - noch heute bildet Lübeck die Basis und den Ausgangspunkt der unternehmerischen Aktivitäten, die sich weltweit erstrecken und von internationaler Bedeutung in den Bereichen Medizintechnik und Sicherheitstechnik sind.
Die Dräger Safety AG & Co. KGaA ist ein Unternehmen der Dräger-Gruppe. Unter dem Leitspruch "Technik für das Leben" entwickelt, produziert und vermarktet die Dräger Safety weltweit Produkte und Dienstleistungen zum Schutz von Mensch und Umwelt, für Anwendung unter Wasser, On- und Offshore, Unter- und Über Tage, in der Luft und im Weltraum. Mit zirka 1500 Mitarbeitern an dem Produktionsstandort Lübeck erwirtschaftet das Unternehmen einen Jahresumsatz von etwa 380 Mio. €.
Der Schutz des Menschen - sei es das Aufspüren bedrohlicher Gefahrstoffe oder der Schutz vor diesen - ist kontinuierliches Element der Dräger Philosophie seit den Ursprüngen des Unternehmens. Sie wird konsequent weitergeführt mit einem ganzheitlichen Gefahrenmanagement - diese Idee steht verbindend über den einzelnen Produktbereichen der Dräger Safety.

1 Preface

Lübeck - the business place rich in tradition and from ancient time center of trade and culture in the North of Germany - was the place Drägerwerk was founded towards the end of the 19th century. Since then the history of the city has always been closely linked with that of the company - still today Lübeck is the basis and starting point of entrepreneurial activities worldwide which have gained international importance in the fields of Medical and Safety Technology.

Dräger Safety AG & Co. KGaA is a company of the Dräger-group. Under the motto 'Technology for Life' Dräger Safety develops, manufactures and sells products for protection of human beings and the environment for applications under water, onshore and offshore, below and above ground, in the air and in space. With its almost 1500 employees at the production facility in Lübeck the company achieves an annual turnover of approx. € 380 million.

Protection of people - be it detection of harmful substances or protection against them - has been a continuous element of the Dräger philosophy since the foundation of the company. It is consequently pursued with comprehensive risk management - this idea unites the individual product divisions of Dräger Safety.

Geltungsbereich

Das vorliegende Qualitätsmanagement - Handbuch beschreibt das Qualitätsmanagementsystem der Dräger Safety.
Es ist gültig für die Dräger Safety AG & Co. KgaA, Lübeck und ihre Niederlassungen.

Scope

This Quality Manual describes Dräger Safety's quality management system and is applicable for Dräger Safety AG & Co. KGaA, Lübeck and its Sales and Service Offices.

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Verbindlichkeitserklärung der Geschäftsführung

Die Geschäftsleitung der Dräger Safety AG&Co. KGaA hat das in diesem Qualitätsmanagement-Handbuch beschriebene Qualitätsmanagementsystem genehmigt und in Kraft gesetzt.
Die Einhaltung der im Qualitätsmanagement-Handbuch getroffenen Festlegungen und der dort aufgeführten Normen und Anweisungen, sowie den darin integrierten Festlegungen zum Umweltschutz ist Verpflichtung für alle Mitarbeiter und eine notwendige Voraussetzung für die Aufrechterhaltung der Zertifizierung des Qualitätsmanagementsystems nach DIN EN ISO 9001 und des Umweltmanagementsystems gemäß DIN EN ISO 14001.

Alle Führungskräfte des Unternehmens sind verpflichtet, dafür zu sorgen, daß die Mitarbeiter die für ihre Arbeit notwendigen Teile des Qualitätsmanagement-Handbuches, Standards und Anweisungen kennen, verstehen und befolgen.

Declaration of Commitment by Management

Dräger Safety AG & Co. KGaA top management has approved and put into force the quality management system described in this Quality Manual.
All employees have a duty to comply with the requirements, standards and instructions set down in the Quality Manual and with the provisions relating to environmental protection laid down therein: such compliance is an essential prerequisite for retaining certification of the company's quality management system in accordance with EN ISO 9001 and environmental management system in accordance with EN ISO 14001.

All the company's managers have a duty to ensure that their staff are familiar with, understand and observe those parts of the Quality Manual, standards and instructions which are of relevance to their work.

Dräger Safety AG & Co. KGaA

Prof. Dr. Albert Jugel **Thomas Holzgreve**

(Unterschriebenes Original liegt im Bereich Qualität, Umwelt, Standards vor)
(Signed original at Quality, Environment, Standards department)

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Quality Manual

1.1 Leitlinien, Vision und Ziele

1.1 Guide Lines, Vision and Goals

We care for your safety

Dräger Safety bietet Leistungen und Produkte mit erkennbarem Nutzen für unsere Kunden an. Ziel ist es, einer der drei Marktführer weltweit zu werden.

Dräger Safety provides performances with obvious benefit for our customers. Target is to be one of three market leaders worldwide.

Dräger Safety ist ein weltweit agierendes Unternehmen im Bereich der Sicherheitstechnik. Durch Konzentration auf unsere Kernkompetenzen lösen wir die Aufgaben unserer Kunden im Bereich des integrierten Risiko Management, in dem wir innovative Produkte, ganzheitliche Service-Lösungen sowie individuelle Unterstützung anbieten und zur Verfügung stellen.

Dräger Safety is a global acting company in the field of safety technology. Through concentration on our core competences we solve our customers' tasks of integrated risk management with innovative products, complete service-solutions and individual support.

Dräger Safety will stetig ihre Marktanteile und den Unternehmenswert erhöhen. Unser Ziel ist eine Kapitalrendite von mehr als 25%.

Dräger Safety strikes for permanent growth of market shares and company value. Our target is a return on capital employed rate more than 25 %.

Unsere Mission ist, die Wettbewerbsfähigkeit strategisch zu sichern und die dafür notwendigen Leistungen besser als die Wettbewerber zu erbringen. Dieser Mission ist alles unterzuordnen und an der Erfüllung ist alles zu messen. Profitables Wachstum und Unternehmenswertsteigerung sind Messwerte für eine erfolgreich realisierte Mission.

Our mission is to secure the competitiveness strategically and to provide a higher level of performance than our competitors. All our activities will be aligned to this mission and will be measured to ensure realisation. Profitable growth and company value are the ratios for a successful realised mission.

Die Mission der ST hat drei Säulen:

The mission of ST has three pillars:

1. Den Bedarf unserer Kunden durch kundenspezifische Leistungen zu decken und damit Nutzen beim Kunden zu erzeugen, ist Grundlage allen markt- und produktstrategischen Handelns. Kunden- und marktorientierte Strategien und Prozesse werden dafür weltweit aufgebaut, ständig verbessert und geführt.

1. Basis of all market and product strategic acting is meeting the demand of our customers with customer tailored performances and generating advantages for our customer. Therefore, customer and market oriented strategies and processes will be globally installed, permanently improved and managed.

2. Wir konzentrieren uns auf unsere Kernkompetenzen und bauen diese weiter aus mit dem Ziel, unsere Überlegenheit gegenüber Wettbewerbern zu sichern. Wir bauen unsere Stärken aus.

2. We concentrate on our core competences with the target to secure our predominance in the market compared to our competitors. We extend our strengths.

3. Eine wichtige Säule für unseren Erfolg sind unsere Mitarbeiter, die überdurchschnittliche Leistungen für die ST erbringen. Wir entwickeln eine Unternehmenskultur, die der entscheidenden Rolle der Mitarbeiter für den Unternehmenserfolg gerecht wird. Dazu haben wir eine Strategie, die die kontinuierliche Entwicklung von Qualifikation und Weiterbildung, Einbeziehung in Entscheidungen, Motivation, Entwicklung von flexiblen Arbeitsmethoden etc. beinhaltet.

3. We rely upon our employees to provide extraordinary performances for ST. We develop a company culture which supports the important role of our employees for the company value. Therefore, we have a strategy which contents the continuous development of qualification and advanced training, involvement in decision making processes, motivation, development of flexible work methods, etc.

Als wesentlichen Schritt zur Sicherung des Geschäftserfolges implementieren wir ein Total Quality Management System, auf die Bedürfnisse des Dräger Konzerns optimiert. Wir nennen dieses System BEST (Business Exellence System). Unser Ziel ist es, uns als weltweit exzellentes Unternehmen zu etablieren.

As an essential step towards ensuring business success, we implement a Total Quality Management System that is optimally tailored to the needs of the Dräger Group. We call this system BEST (Business Exellence System). Our goal is to establish ourselves as an excellent company worldwide.

Die Kernelemente dieses Systems sind:

- Kundenorientierung
- Planungsprozeß
- Prozeßmanagement
- Prozeßverbesserung
- Mitarbeiterbeteiligung

The core elements of this system are:

- Customer focus
- Planning process
- Process management
- Process improvement
- Staff participation.

Durch regelmäßige Reviews verfolgen wir die langfristige Verbesserung der Leistungsfähigkeit aller Geschäftsbereiche.

We perform regular reviews to monitor the long-term improvement in the performance of all business units.

1.2 Qualitäts- und Umweltpolitik

Die Qualitäts- und Umweltpolitik des Dräger Konzerns

Wir sind ein Unternehmen, das Produkte entwickelt, produziert und vertreibt, die das menschliche Atmen ermöglichen, unterstützen und schützen. Die Sicherstellung der Qualität unserer Produkte und Dienstleistungen, der Umwelt- und Gesundheitsschutz sowie die Sicherheit am Arbeitsplatz sind deshalb wesentliche Aufgaben aller Dräger Gesellschaften.
Diese Verpflichtung ist in der Qualitäts- und Umweltpolitik beschrieben. Alle Gesellschaften der Dräger Gruppe setzen diese Politik um und folgen dabei einheitlichen Grundsätzen. Dies gilt unabhängig von den Tätigkeitsbereichen, in denen die Gesellschaften aktiv sind und ohne territoriale Beschränkung.

Wir produzieren ein Höchstmaß an Qualität.

Überall, wo Gesellschaften mit dem Namen Dräger auftreten, wollen wir unseren Kunden Produkte und Dienstleistungen von höchster Qualität und größtmöglichem Wert zur Verfügung stellen und damit ihre Anerkennung und Treue gewinnen.

Dieser Anspruch betrifft nicht nur Produktion, Technik und Service, sondern auch alle anderen Bereiche unseres Unternehmens.

Höchste Qualität erreichen wir durch aktive Mitwirkung aller.

Wir sind davon überzeugt, dass wir die Kundenbedürfnisse nur mit aktiver Unterstützung und entschlossenem Engagement jedes Einzelnen im Unternehmen befriedigen können.

Deshalb fördern wir das Qualitäts- , Umwelt-, Gesundheits- und Sicherheitsbewusstsein unserer Mitarbeiter. Wir stellen sicher, dass sie im Team ihren Beitrag zur Erfüllung der Kundenanforderungen kennen und helfen ihnen dabei, diesen professionell zu erbringen.

Unsere Führungskräfte wirken durch ihr Engagement für die Qualität als Vorbilder für das tägliche Handeln.

Unsere Führungskräfte kennen die Erwartungen unserer Kunden. Sie spornen zur Erbringung höchster Qualität bei allen Leistungen an und unterstützen die Verbesserung der Qualität durch ihr persönliches Engagement.

Die Leistungsfähigkeit und Sicherheit unserer Prozesse soll im Wettbewerb Maßstäbe setzen.

Wir gestalten alle Prozesse derart, dass ihre Ergebnisse die Erwartungen der internen und externen Kunden erfüllen und verbessern ständig deren Leistungsfähigkeit und Wirtschaftlichkeit.

Wir verpflichten uns zu ständiger Verbesserung.

Ein wichtiger Bestandteil unserer Arbeit ist die kontinuierliche Verbesserung all unserer Aktivitäten. Wir lernen gegenseitig aus unseren Erfolgen und Fehlern. Erkannte Fehler beheben wir und beseitigen nachhaltig deren Ursachen.

Wir verpflichten uns dem Schutz der Umwelt.

Der Schutz der Umwelt und der natürlichen Lebensgrundlagen gehören zu unseren obersten Zielen.

Wir wollen in all unseren Arbeitsgebieten eine herausragende Stellung durch hochwertige und umweltgerechte Produkte und Dienstleistungen einnehmen.

Zum Schutz von Luft, Boden und Wasser ergreifen wir aus eigener Initiative vorbeugende Maßnahmen.

Wir betreiben eine offene Informationspolitik gegenüber Mitarbeitern, Nachbarn, Kunden, Behörden und Lieferanten.

Als notwendig Erkanntes nehmen wir auch ohne gesetzliche Verpflichtung oder behördliche Auflagen in Angriff.

Lübeck, im Juli 2000

T. Dräger

1.2 Quality and Environmental Policy

The Quality and Environmental Policy of the Dräger Group

We at Dräger develop, produce and sell products which enable, support and protect human breathing. Guaranteeing the quality of our products and services and ensuring protection of the environment and health as well as safety at the workplace, are thus essential tasks common to all the Dräger companies. This obligation is described in our quality and environmental policy. All the companies of the Dräger Group have a duty to implement this policy, following standard basic principles. This applies irrespectively of the different areas of activity of the individual companies, and without territorial restriction.

We produce the highest possible quality.

Wherever companies appear under the Dräger name and using the Dräger logo, our goal is to provide products and services of the highest quality and value and therefore to be approved by our customers and gain their loyalty.

We not only apply this standard to production, technology and service, but also to all other areas of our company.

Maximum quality requires the active involvement and contribution of everyone.

We firmly believe that we will be able to satisfy the customer's requirements only with the active support and resolute commitment of every individual within the company.

Consequently, we promote and encourage an awareness of quality, environment, health and safety in our employees. We make sure that within the team they are aware of their individual contribution to satisfying customer requirements and we help them to achieve this in a professional manner.

Through their commitment to quality, our managers set examples in our day-to-day work.

Our managers know the expectations of our customers. They encourage their employees to achieve the highest possible quality in every area and contribute to improving quality by dint of their personal commitment.

The efficiency and safety of our processes should aim to set standards for our competitors.

We design all our processes such that their outcomes satisfy the needs of our internal and external customers, and we continuously improve their efficiency and cost-effectiveness.

We are committed to continuous improvement.

An important integral part of our work is the continuous improvement of all our activities. We learn from our own and from each other's successes and mistakes. We identify and correct our mistakes and permanently remove their causes.

We are committed to protecting the environment.

Protection of the environment and the natural foundations of life are amongst our highest priorities.
Our goal is to achieve an outstanding position in all our areas of activity through high quality and environmentally-compatible products and services.
On our own initiative we take preventative measures aimed at protecting the air, soil and water.
We pursue an open information policy vis-à-vis employees, neighbours, customers, authorities and suppliers.
When we recognize the necessity of a particular course of action we are prepared to pursue it even in the absence of any legal obligation or official requirement.

Lübeck, july 2000

T. Dräger

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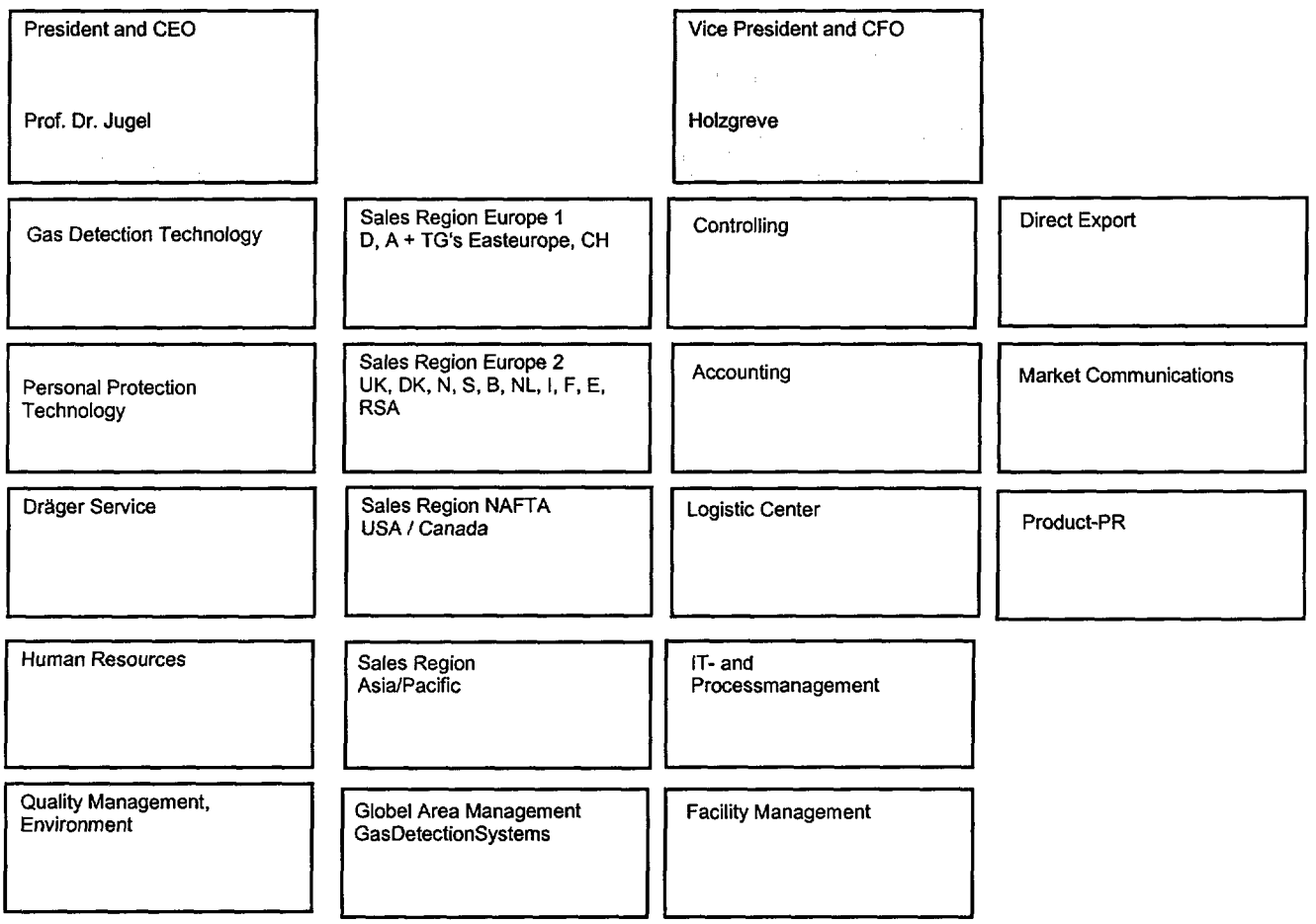
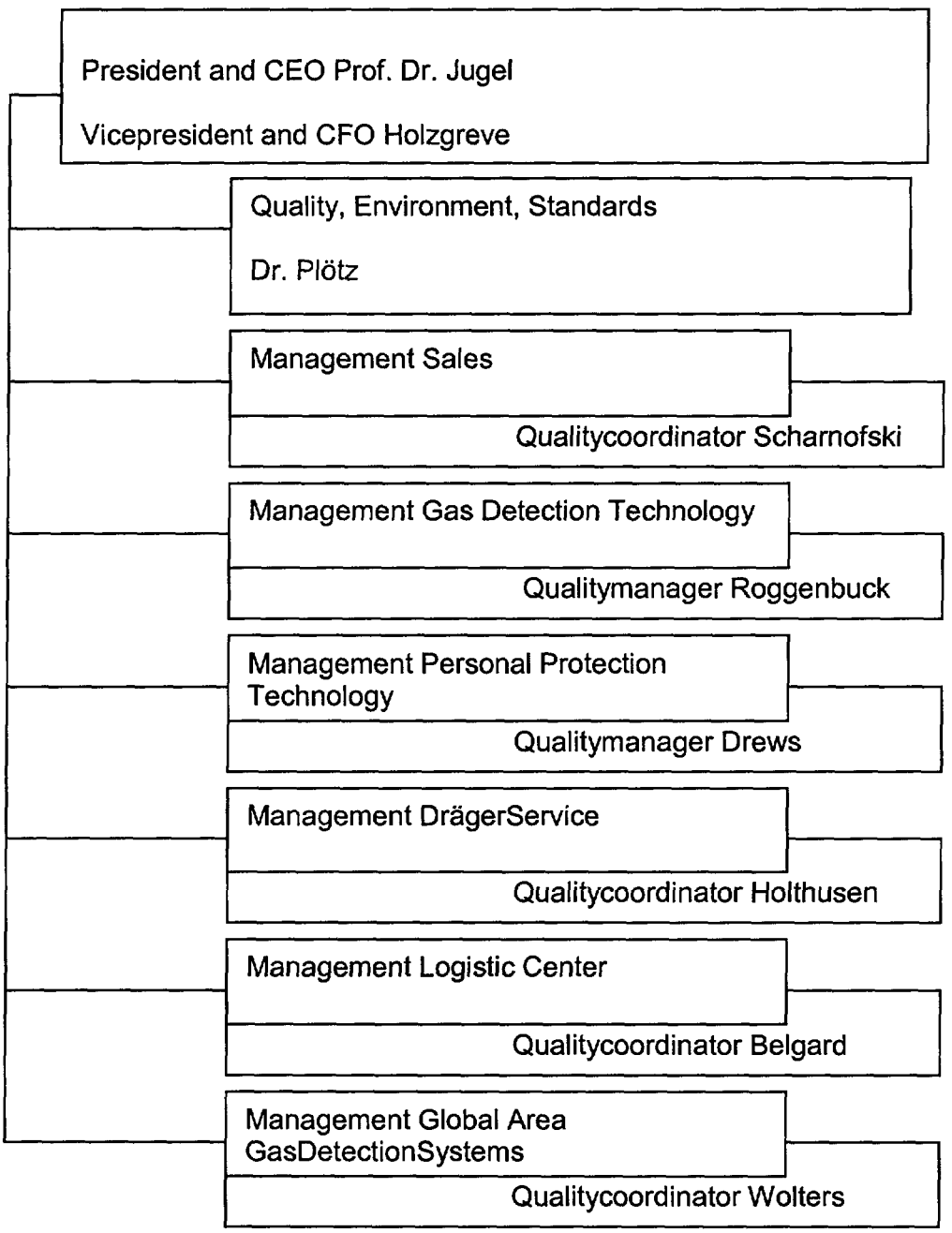
1.3 Organisation / Organization

Organigramm der Dräger Safety AG & Co. KgaA
Organizational Chart Dräger Safety AG & Co. KgaA



Qualitätsmanagement Dräger Safety
Quality Management Dräger Safety



Der Qualitäts -manager/ -koordinator ist ein vom BU-Leiter benannter Mitarbeiter, der für die Koordinierung von qualitätssichernden Aktivitäten in seiner Business Unit (BU) verantwortlich ist.

The quality manager/coordinator is an employee appointed by the BU manager to assume responsibility for the coordination of quality assurance activities within his business unit (BU).

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Umweltmanagementsystem

Zur effizienten Gestaltung des Umweltmanagementsystems sind die Aufgaben, Verantwortlichkeiten und Befugnisse festgelegt, dokumentiert und bekannt gegeben.

Der Vorsitzende des Vorstandes der Drägerwerk AG nimmt die Gesamtverantwortung für den Umweltschutz wahr und sorgt für die Schaffung eines funktionsfähigen Umweltmanagementsystems.

Der Geschäftsführer der Dräger Safety AG&Co. KgaA nimmt die Verantwortung für den Umweltschutz in seinem Verantwortungsbereich wahr. Er sorgt für die Schaffung eines funktionsfähigen Umweltmanagementsystems.
Beauftragter der obersten Leitung im Sinne der DIN EN ISO 14001 ist der Leiter des Bereiches Qualität, Umwelt, Standards.
Weitere Umweltbeauftragte wurden gemäß festgelegter Standards ernannt.

(Abschnitt 9)

Environmental Management System

For the efficient design of the environmental management system, the tasks, responsibilities and authorities have been defined, documented and communicated.

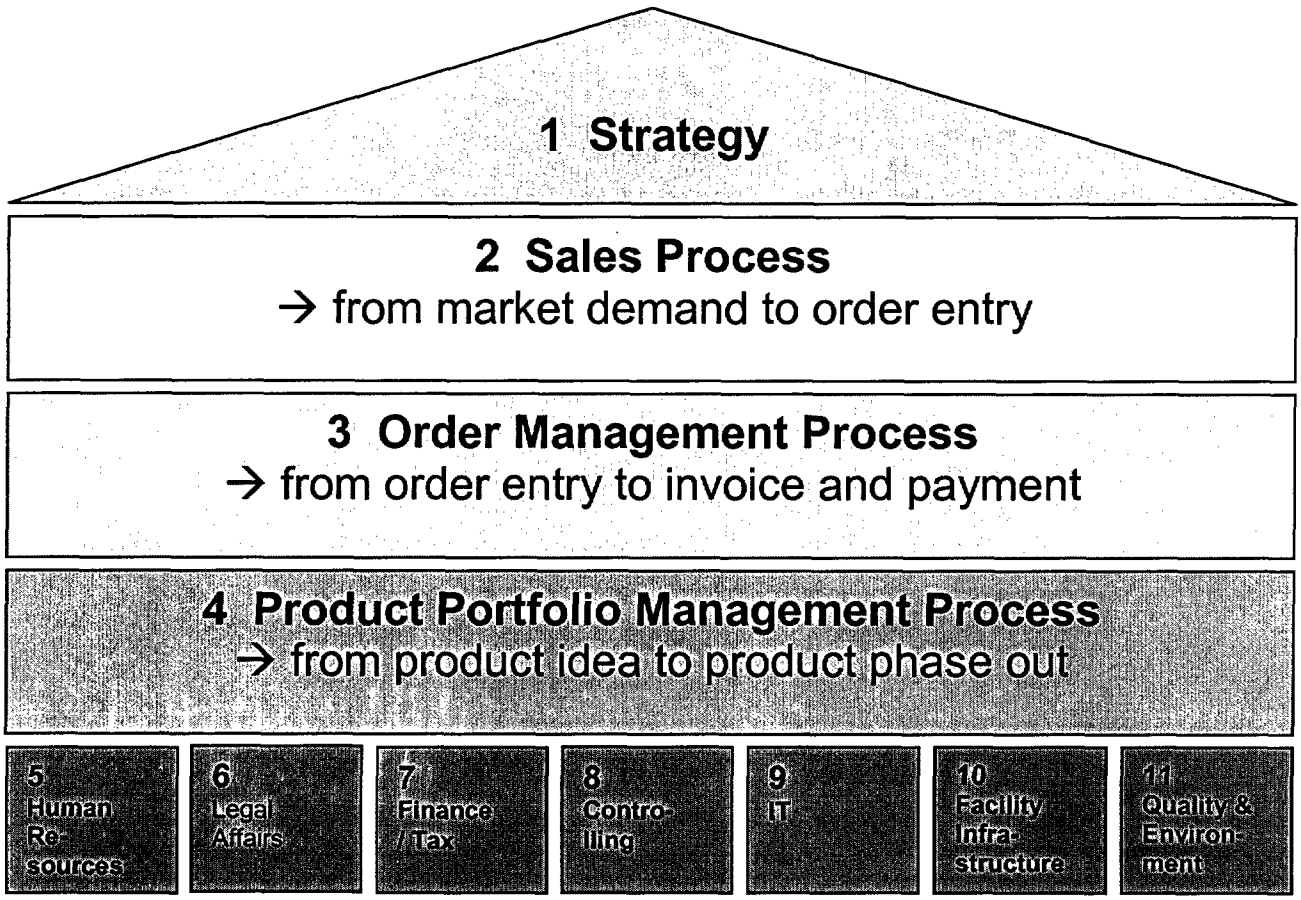
The Chairman of the Executive Board of Drägerwerk AG has overall responsibility for environmental protection and for establishing a functional environmental management system.

The President and CEO of Dräger Safety AG & Co. KGaA has responsibility for environmental protection within his area of responsibility and for establishing a functional environmental management system.
The head of Quality, Environment, Standards holds the position of management representative within the meaning of EN ISO 14001.
Further environmental officers have been appointed in accordance with the established procedures.

(Section 9)

1.4 Ablauforganisation / Industrial Engineering

Unsere identifizierten Prozesse sind folgendermaßen strukturiert:
Our identified processes are structured as following:



2 Prinzipien unserer Vorgehensweise

Die nachfolgenden Grundsätze sind die Basis unseres Handelns. In den unternehmensweiten BEST-Schulungen haben wir die notwendigen Methoden unseren Mitarbeitern nahegebracht. Die Anwendung dieser Prinzipien wird in den regelmäßigen BEST-Reviews hinterfragt.

Unsere Qualitätsmanagement-Grundsätze

Kundenorientierung
Konsequente Kundenorientierung ist die Voraussetzung für unseren geschäftlichen Erfolg. Es kommt darauf an, die Kundenbedürfnisse nicht nur zu erfüllen, sondern zu übertreffen und zukünftige Bedürfnisse vorwegzunehmen. Deshalb richten wir die Organisation unseres Unternehmens auf die Kundenbedürfnisse aus und ermitteln regelmäßig die Zufriedenheit unserer Kunden.

Führung
Durch unsere Führung geben wir unseren Mitarbeitern ein klares Leitbild. Wir setzen anspruchsvolle Ziele und machen Vorgaben, wie diese zu erreichen sind. Wir sorgen dafür, dass unsere Strategie die Zukunft des Unternehmens sicherstellt.

Einbeziehen der Menschen
Unsere Mitarbeiter machen sich die Ziele des Unternehmens zu eigen und sind in Entscheidungen und Prozessverbesserungen einbezogen. Sie stellen ihr persönliches Entwicklungspotential in den Dienst des Unternehmens.

Prozessorientierter Ansatz
Wir identifizieren die externen und internen Kunden und Lieferanten unserer Geschäftsprozesse. Wir sorgen dafür, dass die Prozesse effizient die Kundenbedürfnisse erfüllen.

2 The Principles of our Procedure

The principles set out below form the basis for our activities. In the company-wide BEST training courses, our employees have been taught the methods they need to apply these principles. The regular BEST reviews verify that the principles are being applied.

Our Quality Management Principles

Customer Focus
Consistent customer focus is a prerequisite for our business success. We must not only meet but surpass our customer's needs, and anticipate future requirements. We therefore gear our company's organization to our customers' requirements and regularly review customer satisfaction.

Leadership
Through our leadership, we provide our staff with clear role models. We set ambitious goals and instruct our staff in how to achieve these goals. We ensure that our strategy will secure our company's future.

Staff Participation
Our employees adopt the company's goals and are involved in decision-making and process improvements. They place their personal development potential at the company's service.

Process Approach
We identify the external and internal customers and suppliers of our business processes, and make sure that our processes efficiently meet our customers' needs.

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Systemorientierter Managementansatz
Wir stellen sicher, dass die Teilprozesse unseres Unternehmens effektiv zusammenarbeiten und das Gesamtziel unseres Unternehmens erreichen. Wir messen den Erfolg unserer Teilprozesse und den Gesamterfolg des Unternehmens.

System-Based Management Approach
We ensure that the subprocesses of our company interact effectively and achieve our company's overall objectives. We measure the success of our subprocesses and the overall success of the company.

Ständige Verbesserung
Wir setzen ehrgeizige, aber realistische Ziele, stellen die entsprechenden Werkzeuge zur Zielerreichung zur Verfügung und sorgen dafür, dass die kontinuierliche Verbesserung unseres Unternehmens fester Bestandteil der Aufgaben der Mitarbeiter ist. In den BEST Schulungen haben wir die Mitarbeiter in den Methoden trainiert - mit den laufenden Problemlösungs- und Qualitätsverbesserungsprozessen entwickeln wir unser gesamtes Unternehmen in allen Bereichen weiter.

Continuous Improvement
We set ambitious yet realistic goals, provide the tools needed to achieve these goals and ensure that the continuous improvement of our company is an integral part of our employees' work. In the BEST courses we trained our staff in the necessary methods, and through ongoing problem solving and quality improvement processes we are further developing our entire company in all its departments.

Faktenbasierte Entscheidungen
Unsere Entscheidungen basieren auf Daten und Informationen, die wir in gesicherten Prozessen beschaffen und bewerten. Aus der Messung unserer Prozessergebnisse und der Zufriedenheit unserer Kunden leiten wir die Verbesserungsmaßnahmen ab.

Fact-Based Decision-Making
We base our decisions on data and information which we obtain and evaluate from reliable processes. From our measurement of process results and the satisfaction of our customers, we determine the necessary improvement actions.

Lieferantenbeziehungen zum gegenseitigen Nutzen
Wir wissen, dass wir unsere Kunden nur zufrieden stellen können, wenn wir unsere Lieferanten von Anfang an in diese Aktivitäten einbinden. Wir wollen mit unseren Lieferanten vertrauensvoll zusammenarbeiten, um die Zufriedenheit unserer Kunden langfristig zu sichern.

Supplier Relations for Mutual Benefit
We are aware that we can only satisfy our customers if we involve our suppliers in these activities from the outset. We want to work together with our suppliers on a basis of trust so as to guarantee satisfaction of our customers.

Unsere Umweltmanagement Grundsätze

Aus der Dräger Umweltpolitik haben wir unsere Umweltmanagement Grundsätze abgeleitet.

Langlebigkeit unserer Produkte
Wir entwickeln, fertigen und vertreiben Produkte, die sich durch Langlebigkeit auszeichnen und dadurch einen wesentlichen Beitrag zur Schonung der Umwelt leisten. Der optimale Schutz der Anwender unserer Produkte ist vorrangiges Ziel unserer Bestrebungen und wird mit einem Höchstmaß an Umweltschutz kombiniert.

Recycling
Wir recyceln unsere Produkte und praktizieren die Produktrücknahme. Für Produkte, die nur für den Einmalgebrauch konzipiert oder nicht mehr nutzbar sind, bieten wir die fachgerechte und umweltverträgliche Entsorgung an.

Entwicklung und Konstruktion unserer Produkte
Bei der Entwicklung unserer Produkte legen wir großen Wert auf den Einsatz umweltschonender Materialien und den Verzicht auf nicht Wiederverwendbare. Ein modularer Aufbau unserer Geräte sowie die Vermeidung von Verbundstoffen sind weitere wichtige Aspekte zum Schutz der Umwelt. Diese wesentlichen Punkte werden mit der Entwicklung umweltschonender Fertigungsverfahren kombiniert. Diese Vorgehensweise ist verbindlich in Dräger Safety Standards geregelt.

Vermeidung und Minimierung von Umweltauswirkungen in der Produktion
Produktionsprozesse werden in der Dräger Safety auf ihre Umweltrelevanz bewertet und, wo möglich, Verbesserungsmaßnahmen initiiert. Dies wird wesentlich durch ein wirksames Energiecontrolling unterstützt. Die Minimierung des Wasser- und Energieverbrauches ist ein kontinuierlicher Prozess.

Our Environmental Management Principles

Out of the Dräger Environmental Policy we derived our Environmental Management Principles.

Long Product Service Life
We develop, manufacture and sell products which offer a long service life and therefore contribute significantly to protecting the environment. The overriding objective of all our efforts is to protect the users of our products to the best of our ability – we combine this with the maximum possible environmental protection.

Recycling
We recycle our products and operate a product return scheme. We offer our customers a disposal service to ensure that products designed for single use only or which can no longer be used are disposed of properly, in a way that is compatible with the environment.

Product Development and Design
Even at the design and development stage, we are committed to using as many environmentally-friendly materials and as few non-reuseable materials as possible in our products. The modular design of our devices and the avoidance of composite materials are further important steps towards protecting the environment. We combine these essential aspects with the development of environmentally-compatible production methods. This approach is binding and set down in the Dräger Safety Standards.

Avoidance and Minimization of Environmental Impact in Production
At Dräger Safety, production processes are evaluated with respect to their environmental relevance, improvements being initiated wherever possible. This is helped to a major extent by effective energy controlling: minimization of water and energy consumption is a continuous process.

Einbeziehung unserer Vertragspartner in unsere Umweltschutzbemühungen
Lieferanten und Fremdfirmen beziehen wir in unsere Umweltschutzkonzepte ein. Umweltrelevante Planungen, Entscheidungen und Maßnahmen werden mit unseren Vertragspartnern unter Berücksichtigung aller ökologischen und ökonomischen Kriterien umgesetzt.

Involvement of Contractual Partners in Our Environmental Protection Efforts
We involve our suppliers and external partners in our environmental protection programmes. Before plans, decisions and activities of relevance to the environment are implemented, full consideration is given to all ecological and economic criteria.

Vorsorgemanagement
Gefährdungspotentiale werden kontinuierlich bewertet und, wo erforderlich, Maßnahmen zur Minimierung initiiert. Dies ist zentraler Punkt unseres effektiven, auf Vorausschau aufgebauten Brandschutzmanagements.

Preventive Management
Potential risks are assessed continuously, with action taken to minimize such risks wherever necessary. This is a central element of our effective and forward-looking fire protection management policy.

Umweltgerechtes Verhalten im Gesamtunternehmen
Umweltgerechtes Verhalten wird in allen Bereichen der Dräger Safety gefördert. Hierzu werden wechselnde Aktionen zur Sensibilisierung des Umweltbewusstseins der Mitarbeiter durchgeführt. Zentrale Bedeutung kommt hierbei der Ideenbörse und der Kommunikation in der gesellschaftsübergreifenden Mitarbeiterzeitung „dialog“ zu.

Environmental Awareness Throughout the Company
Environmental awareness and behaviour is encouraged in all the departments of Dräger Safety. A variety of alternating activities are carried out to sensitize staff to environmental issues. In this respect, a central role is played by the ideas forum and communication via the Dräger Group staff newspaper "dialog".

Arbeits-und Gesundheitsschutz
Unser Ziel ist die Umsetzung des Präventionsgedankens, alle Prozesse störungs- und fehlerfrei ablaufen zu lassen. Mitarbeiter aller Ebenen identifizieren sich mit dem Arbeits- und Gesundheitsschutzgedanken. Maßnahmen hierzu werden geplant und die Umsetzung kontrolliert. Die Berücksichtigung gesicherter, arbeitswirtschaftlicher und arbeitsmedizinischer Erkenntnisse führen zur kontinuierlichen Verbesserung dieser Aspekte in der Dräger Safety.

Occupational Safety and Health
Our goal is to encourage a preventive mentality and ensure that all processes run smoothly and correctly. Staff at all levels can identify with the concept of occupational safety and health. Occupational safety measures are planned and their implementation monitored. Occupational safety at Dräger Safety is continuously improved to reflect the latest knowledge of labour management.

3 Anwendungsbereich

Das Managementsystem, aufbauend auf die Qualitäts- und Umweltpolitik, beschreibt die internen Prozesse, die eine ständige Bereitstellung von Produkten und die ständige Erhöhung der Kundenzufriedenheit, unter Berücksichtigung ökonomischer und ökologischer Gesichtspunkte, sicherstellen.
Die Erfüllung und Einhaltung von Kunden- / und behördlichen Anforderungen werden gemäß der Vorgaben der DIN EN ISO 9001 Qualitätsmanagementsysteme - Anforderungen" und dem internationalen Standard DIN EN ISO 14001 „Umweltmanagementsysteme – Spezifikation mit Anleitung zur Anwendung" umgesetzt.
Diese Anforderungen sind an die Gegebenheiten der Dräger Safety AG & Co. KgaA angepasst und werden anhand nachgeordneter interner Drägervorgaben (Abschnitt 9) geregelt.
Das dokumentierte Managementsystem wird regelmäßig durch Systemaudits auf seine Wirksamkeit, Aufrechterhaltung und kontinuierliche Verbesserungsprozesse überprüft.
Das System wird regelmäßig von folgenden externen Stellen auditiert:

- TÜV-CERT-Zertifizierungsstelle der TÜV Nord Zertifizierungs- und Umweltgutachtergesellschaft mbH (Zertifikat gemäß DIN EN ISO 9001 und DIN EN ISO 14001)

- DMT- Deutsche Montan Technologie GmbH
  (Zertifikat gemäß Richtlinie des Rates 89/686/EWG über persönliche Schutzausrüstungen;
  Zertifikat gemäß Richtlinie 94/9/EG Geräte und Schutzsysteme zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen)

- NIOSH (National Institute for Occupational Safety and Health, USA)

- Siemens (Bestätigung entsprechend Kerntechnische Anlagen 1401)

3 Field of Application

The management system, building upon the quality and environmental policy, describes the internal processes which, taking economic and ecological factors into account, ensure that products are constantly available and customer satisfaction is continuously increased.
Customer and regulatory requirements are met and complied with in accordance with the provisions of EN ISO 9001 "Quality management systems - Requirements" and the international standard EN ISO 14001 "Environmental management systems – Specification with guideance for use".
The requirements contained in these standards have been adapted to the situation at Dräger Safety AG & Co. KgaA and are regulated on the basis of subordinated internal Dräger regulations (Section 9).
System audits are regularly performed to check that the documented management system is effective and maintained and that continuous improvement processes are carried out.
The system is regularly audited by the following external bodies:

- TÜV-CERT-Zertifizierungsstelle der TÜV Nord Zertifizierungs- und Umweltgutachtergesellschaft mbH (Certificate in acc. with EN ISO 9001 and EN ISO 14001)

- DMT-Deutsche Montan Technologie GmbH
  (Certificate in acc. with Council Directive 89/686/EEC on personal protective equipment;
  Certificate in acc. with Directive 94/9/EC Equipment and protective systems intended for use in potentially explosive atmospheres)

- NIOSH (National Institute for Occupational Safety and Health, USA)

- Siemens (confirmation in acc. with German Regulatory Guide for Nuclear Power Plants KTA 1401)

4 Qualitäts- und Umweltmanagement-system

Das Qualitätsmanagementsystem der Dräger Safety AG & Co KgaA, aufbauend auf der Qualitäts- und Umweltpolitik, beschreibt die Vorgehensweise in allen unseren Prozessen in nachvollziehbarer Weise gemäß den Anforderungen der ISO 9001 und ISO 14001. Wir identifizieren die Prozesse, die für unseren Geschäftserfolg wichtig sind, legen fest, wie diese Prozesse überwacht werden und zusammenwirken und verbessern diese Prozesse kontinuierlich. Dadurch erreichen wir ein hohes Maß an Kundenbindung, flexible und schnelle Reaktion auf unsere Märkte, Verringerung unserer internen Durchlaufzeiten und Verbesserung unserer Ergebnisse.

In das Qualitätsmanagemensystem integriert ist das gemeinsame Umweltmanagement aller Dräger Gesellschaften am Standort Lübeck, es ist in einem gemeinsamen, für alle Dräger Gesellschaften am Standort Lübeck verbindlichen, Umweltmanagement Handbuch der Drägerwerk AG beschrieben (Abschnitt 9).
Weitgehend gleiche Anforderungen an die Dräger Gesellschaften sowie die starke räumliche und auch logistische Vernetzung am Standort Lübeck stellen den wesentlichen Nutzen eines gemeinsamen Umweltmanagements dar.

Wichtige umweltrelevante Tätigkeiten und Aufgaben, wie die Entsorgung und Lagerung, werden von Dräger Interservices für alle Dräger Gesellschaften ausgeführt. Dies unterstützt die gleichrangige Behandlung des Umweltschutzes für den gesamten Standort Lübeck.

Im Rahmen des Umweltmanagement Systems übernimmt die Drägerwerk AG die Zuständigkeit für Kernelemente gemäß DIN EN ISO 14001, wie beschrieben im gemeinsamen Umweltmanagementhandbuch (Abschnitt 9).

4 Quality and Environmental System

The quality management system in place at Dräger Safety AG & Co. KGaA, building upon the quality and environmental policy, clearly and comprehensibly describes the procedure in all our processes, in accordance with the requirements of ISO 9001 and ISO 14001. We identify the processes which are important for our business success, lay down how these processes are monitored and interact, and continuously improve these processes. This allows us to achieve a high level of customer loyalty, react quickly and flexibly to our markets, shorten our internal throughput times and improve our results.

The environmental management policy shared by all Dräger companies in Lübeck is integrated into the quality management system and described in a Drägerwerk AG environmental manual which is binding for all Lübeck-based Dräger companies (Section 9). The fact that the requirements for the Dräger companies are largely the same, coupled with the close spatial and logistical links between the companies at the Lübeck plant, makes clear the benefit of a shared environmental management policy.

Important tasks and activities of relevance to the environment, such as disposal and storage, are performed for all the Dräger companies by Dräger Interservices. This further promotes the equal treatment of environmental protection throughout the Lübeck plant.

Within the framework of the environmental management system, Drägerwerk AG is responsible for core elements in accordance with EN ISO 14001, as described in the Environmental Management Manual. (Section 9)

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Dokumentation

Das Qualitäts- und Umweltmanagementsystem der Dräger Safety wird in diesem Handbuch und in weiteren Prozessbeschreibungen und Standards dokumentiert.
Dieses Handbuch wird vom Bereich Qualität, Umwelt, Standards erstellt und herausgegeben und von der Geschäftsleitung in Kraft gesetzt. Das Handbuch enthält sowohl die deutsche als auch die englische Sprachversion. Es wird den Mitarbeitern in geeigneter Weise elektronisch zur Verfügung gestellt. Die Mitarbeiter werden über Änderungen des Handbuches informiert. Die Besitzer von gedruckten Ausgaben dieses Handbuches haben die Verpflichtung, ihre Exemplare bei Änderungen jeweils zu aktualisieren. Für externe Besitzer von Handbüchern wird dies vom Bereich Qualität, Umwelt, Standards übernommen.
In diesem Handbuch sind die Anforderungen des gemeinsamen Umweltmanagementsystems am Standort Lübeck integriert und für die Dräger Safety umgesetzt. Es beschreibt in kurzer Form die Prozesse des Qualitäts- und Umweltmanagementsystems und deren Wechselwirkungen und verweist im Abschnitt 9 auf weitere dokumentierte Standards.

Documentation

The quality and environmental management system at Dräger Safety is documented in this manual and in various other process descriptions and standards.
This manual is compiled and issued by Quality, Environment, Standards and put into force by top management. The manual includes both a German and an English language version. It will be made available to staff in an appropriate electronic form. Employees will be informed of any changes to the manual. Owners of printed copies of this manual have a duty to ensure that their copies are updated whenever changes are made. In the case of external owners of manuals, this will be done by Quality, Environment, Standards.
This manual sets out the requirements of the joint environmental management system of the Lübeck-based Dräger companies and how these requirements are to be met by Dräger Safety. It briefly describes the processes of the quality and environmental management system and their interactions and refers in Section 9 to other documented standards.

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4.1 Allgemeine Anforderungen

4.1 General Requirements

4.2 Dokumentations-anforderungen

Lenkung von Dokumenten
Die Lenkung von Dokumenten erfolgt nach einem dokumentierten Standard .
Dieser Standard regelt den ordnungsgemäßen Informationsfluß innerhalb des Unternehmens und zu Lieferanten, Kunden und anderen Interessenspartnern.
Verantwortlich für die Umsetzung dieser Vorgaben sind die Bereiche, in denen relevante Dokumente erstellt, herausgegeben, zur Verfügung gestellt und geändert werden.
Alle relevanten Dokumente werden vor ihrer Herausgabe bezüglich der Angemessenheit und der Konformität mit dem Qualitätsmanagementsystem genehmigt und freigegeben. Wenn bei der Bewertung von Dokumenten erkannt wird, dass diese aktualisiert werden müssen, durchlaufen die Dokumente ebenfalls diesen Genehmigungszyklus.
Üblicherweise werden die freigegebenen Dokumente den Mitarbeitern in elektronischer Form zur Verfügung gestellt, durch entsprechende dokumentierte Vorgehensweisen in den verantwortlichen Stellen wird sichergestellt, dass der Inhalt des freigegebenen Dokumentes mit der elektronischen Darstellung identisch ist und der aktuelle und freigegebenen Änderungsstand für alle Verwender ersichtlich ist.
Für Dokumente, die in Papierform verteilt werden führt die herausgebende Stelle eine Dokumentation, aus der der Verteiler und der aktuelle Änderungsstand der Dokumente hervorgeht. Externe Normen und Regelwerke werden in unsere interne Dokumentation von den zuständigen Stellen aufgenommen und dann intern nach der obigen Vorgehensweise gelenkt.

4.2 Documentation Requirements

Control of Documents
Documents are controlled in accordance with a documented standard .
This standard governs the proper flow of information within the company and to suppliers, customers and other interested parties. The departments in which relevant documents are compiled, issued, made available and changed are responsible for complying with these requirements.
Prior to issue, all relevant documents are approved for adequacy and for compliance with the quality management system and released. If documents are found to need updating when they are reviewed, they also undergo this approval process.
Normally, the released documents will be made available to staff in electronic form. Appropriate documented procedures in the competent departments are carried out to ensure that the content of the released document is identical with that of the electronic version and that the latest released revision status is clearly visible to all users.
In the case of documents which are distributed in paper form, the issuing department compiles documentation which clearly shows the mailing list and current revision status of the documents. External standards and regulations are included in our internal documentation by the competent departments and then controlled internally in accordance with the procedure described above.

Lenkung von Aufzeichnungen

In unseren Prozessen entstehen an vielen Stellen und Gelegenheiten Aufzeichnungen, die dazu dienen die Konformität unserer Vorgehensweise mit unseren Anforderungen nachzuweisen. Diese Aufzeichnungen beziehen sich dabei sowohl auf die Durchführung einzelner Prozessschritte, als auch auf den Nachweis der Konformität unserer Produkte und Dienstleistungen mit den festgelegten Anforderungen. Generell wird in allen Prozessen festgelegt, welche Aufzeichnungen in welcher Form zu erstellen sind, wie diese zu kennzeichnen und zu archivieren sind. Für die Aufbewahrungsfristen gelten die gesetzlichen Vorgaben, falls nicht anders festgelegt, werden relevante Aufzeichnungen 11 Jahre aufbewahrt. Diese Regelungen gelten auch für Aufzeichnungen bezüglich der Umweltaspekte unseres Handelns. Die Details zur Lenkung der Aufzeichnungen befinden sich in den dokumentierten Standards im Abschnitt 9.

Control of Records

Within our processes, records intended to provide evidence of the conformity of our procedure with our requirements are generated at many points and on many occasions. These records relate both to the performance of individual process stages and to evidence of conformity of our products and services with the specified requirements. In general, it is specified for all processes which records need to be compiled in which form and how they are to be identified and stored. The statutory regulations apply to the retention periods: unless specified otherwise, relevant records are stored for 11 years. These regulations also apply to records relating to environmental aspects of our activities. Details of the control of records are to be found in documented standards in Section 9

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5 Verantwortung der Leitung

Kundenorientierung

Q- Politik

Qualitätsziele

Beauftragter der obersten Leitung

Beauftragter der obersten Leitung im Sinne der DIN EN ISO 9001 und DIN EN ISO 14001 ist die Leitung Qualität, Umwelt, Standards. Sie ist von der Geschäftsleitung direkt beauftragt, legt die Richtlinien für das Qualitäts- und Umweltmanagement fest und aktualisiert die Vorgaben für die Umsetzung des Qualitäts- und Umweltmanagementsystems in den operativen Bereichen. Der Beauftragte ist in Fragen des Qualitats- und Umweltmanagementsystems Ansprechpartner für Kunden und Lieferanten, Institutionen und Behörden.

Die Aufgaben von Qualität, Umwelt, Standards sind wie folgt zusammengefasst:

- Vorgaben und Regeln für die Umsetzung eines einheitlichen Qualitäts- und Umweltmanagementsystems im Dräger Safety Konzern aufstellen und aktualisieren.
- Überwachung der Einhaltung der Vorgaben und Regeln des Qualitäts- und Umweltmananagementsystems durch interne Qualitätsaudits.
- Darstellung und Bewertung der Einhaltung des Qualitäts- und Umweltmanagementsystems durch Erstellen von Qualitäts- und Umweltreports.

5 Management Responsibility

Customer Focus

Quality Policy

Quality Objectives

Management Representative

The head of Quality, Environment, Standards holds the position of management representative within the meaning of EN ISO 9001 and EN ISO 14001. The management representative is appointed directly by top management, lays down the guidelines for quality and environmental management and updates the goals for implementation of the quality and environmental management system in the operational units. The management representative acts as point of contact for customers and suppliers, institutions and authorities in all questions relating to the quality and environmental management system.

The duties of Quality, Environment, Standards can be summarized as follows:

- Establishing and updating targets und rules for the implementation of a uniform quality and environmental management system within the Dräger Safety Group.
- Conducting internal quality audits to monitor compliance with the targets and rules of the quality and environmental management system.
- Compiling quality and environmental reports to illustrate and evaluate compliance with the quality and environmental management system.

- Analysieren und Bewerten von neuen Qualitäts- und Umweltanforderungen aus gesetzlichen Auflagen, externen Vorgaben und Kundenforderungen und deren Umsetzung in das Managementsystem.
- Analysing and evaluating new quality and environmental requirements stemming from laws, external targets and customer demands, and their incorporation into the management system.

- Verwalten und Verteilen von übergeordneten Prozessbeschreibungen, Standards, internen und externen Vorschriften.
- Managing and distributing higher-level process descriptions, standards, internal and external regulations.

Die operative Umsetzung des Qualitäts- und Umweltmanagementsystems findet in den Business Units statt.
Folgende Aufgaben werden in den Business Units wahrgenommen:

Operational implementation of the quality and environmental management system takes place in the business units.
The following tasks are performed in the business units:

- Auditieren und Bewerten der Qualitätsfähigkeit von Lieferanten
- Auditing and reviewing the quality capability of suppliers

- Erstellen und Pflege von Prüfvorgaben und -plänen für die Fertigung und Beschaffung
- Compiling and updating test instructions and plans for production and purchasing

- Planen und Durchführen von Prüfungen zur Sicherung der Qualität von Zulieferprodukten, Chemikalien, Halbzeugen, Werkstoffen, Komponenten und Geräten
- Planning and conducting tests to ensure the quality of supplied products, chemicals, semi-finished products, materials, components and devices

- Mitwirken bei Qualitätssicherungsplänen und bei Projekt Reviews
- Participating in the preparation of quality assurance plans and performance of design reviews

- Mitwirken bei der Spezifikation, Erstellung und Pflege von Prüfmitteln
- Participating in the specification, production and updating of test equipment

- Einleiten und Überwachen von Maßnahmen zur Fehlervermeidung
- Initiating and monitoring actions to avoid errors

- Ernennung von Mitarbeitern in den Organisationseinheiten bezüglich Qualitätstätigkeiten
- Appointing staff in the business units to perform quality activities

- Schulung der Fertigungsmitarbeiter in Qualitätssicherungstätigkeiten
- Training production staff in quality assurance activities

- Einleiten und Überwachen von Korrektur- und Qualitätsverbesserungs-maßnahmen aufgrund interner und externer Qualitätsinformationen
- Initiating and monitoring corrective action and quality improvement measures in response to internal and external quality information

- Überwachung der Einhaltung der Regeln des Qualitätsmanagementsystems
- Darstellen der Qualitätssicherungsaktivitäten intern/extern
- Überwachen, Kalibrieren und Verwalten von Prüfmitteln
- Angebots- und vertragspezifische Qualitätssicherungsaktivitäten planen und durchführen

In den folgenden Abschnitten des Qualitätsmanagement-Handbuches sind die Beschreibungen der Aufgaben weiter detailliert.
Die Leitungen der verschiedenen Business Units sind verantwortlich für die Umsetzung der Vorgaben des Qualitäts- und Umweltmanagementsystems. Sie werden darin von Qualitätskoordinatoren / Qualitätsmanagern unterstützt.

- Monitoring compliance with the rules of the quality management system
- Internal/external presentation of quality assurance activities
- Monitoring, calibrating and administrating test equipment
- Planning and carrying out quality assurance activities specific to tenders and contracts

These tasks are described in more detail in the following sections of the Quality Manual.

The managers of the various business units are responsible for implementing the quality and environmental management system as instructed. The quality coordinators/quality managers help them in this task.

Kommunikation

Der Dräger Safety Konzern ist mit dem Qualitätsreporting in die Kommunikation des gesamten Dräger Konzerns gemäß der Qualitätsreporting Richtlinie eingebunden.
Alle produzierenden Einheiten erstellen je Quartal einen Bericht über den Qualitätsstatus.
Eine Zusammenfassung dieser Berichte für den Safety Konzern wird vom Bereich Qualität, Umwelt, Standards erstellt und dem Management zur Verfügung gestellt. Auf den regelmäßigen Sitzungen des Führungskreises der Dräger Safety, auf den halbjährlich stattfindenden internationalen Strategiemeetings und auf den Vertriebs- und Servicetagungen wird der Qualitätsstatus in Form der Ziele, der Strategie der Zielerreichung und des jeweiligen Standes der Zielerreichung dargestellt.
Das Managementreview wird im gesamten Führungskreis kommuniziert. Innerhalb der Einheiten erfolgt die Kommunikation über Qualitätsziele und den Stand der Umsetzung gemäß interner Vorgaben.
(Abschnitt9)

Communication

Through its quality reporting, the Dräger Safety Group is integrated into the communication processes of the entire Dräger Group.
All producing business units compile a quarterly report of their quality status.
A summary of these reports for the Safety Group is prepared by Quality, Environment, Standards and submitted to management. The Quality status is pictured in terms of targets, strategy of reaching them and the current status of each target. This subject of communication is part of the periodical meetings of the Management circle of Draeger Safety, semi-annual international strategy meetings and of sales and service conferences. The management review is being communicated in the Management circle.
Within the business units, communication regarding quality objectives and implementation status takes place in accordance with internal regulations.
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QualitätsManagement - Handbuch
Quality Manual

Managementbewertung

Die festgelegten Regelungen des Qualitätsmanagement- Handbuchs und der Dräger Safety Standards und Anweisungen werden anhand von internen Qualitätsaudits, durch Auswertung von Qualitätsaufzeichnungen, Daten-, Fehler- und Qualitätsanalysen regelmäßig hinsichtlich ihrer Wirksamkeit überprüft. Das Managementsystem wird durch akkreditierte Zertifizierungsstellen auditiert. Die Leitung Qualität, Umwelt, Standards verfaßt jährlich einen Qualitätsbericht, dieser wird der Geschäftsleitung vorgestellt.

In diesem Bericht werden die Ergebnisse der Audits, die Ergebnisse der Kundenzufriedenheitsanalysen und der Reklamationsauswertungen, die Prozessergebnisse und der Stand der Korrektur und Vorbeugemaßnahmen (sowie ggfs. Folgeaktivitäten aus früheren Massnahmen) dargestellt und bewertet. Der Qualitätsbericht bildet mit Informationen und Analysen aus den Business Units unter anderem die Basis des Management Reviews durch die Geschäftsleitung. Die Geschäftsleitung entscheidet in diesem Review über Massnahmen zur Verbesserung des Qualitätsmanagements-systems und der zugrundeliegenden Prozesse, über notwendige Produktverbesserungen und über die notwendigen Resourcen.

Management Review

Internal quality audits are conducted, quality records evaluated and data, error and quality analyses performed to check the effectiveness of the rules and regulations of the Quality Manual and of the Dräger Safety standards and instructions. The management system is audited by accredited certification bodies. The head of Quality, Environment, Standards produces an annual quality report which is submitted to top management. The quality report, together with information and analyses from the business units, forms the basis for the management review.

This report pictures and assesses results of audits, customer satisfaction- and claims analysis, process performance and status of corrective and preventive actions (incl. follow up activities out of former measures).
The quality report with information and analysis out of the business units forms the basis for the management review of the top management.
In this review the executive board decides about measures to be taken for the improvement of the quality management system and the underlying processes, about necessary product-improvements and the ressources needed.

Umweltaspekte

Umwelteinwirkungen, die von unseren Tätigkeiten, Produkten und Dienstleistugnen ausgehen werden systematisch erfasst, bewertet und dokumentiert.

Environmental Aspects

The effects on the environment of our activities, products and services are systematically recorded, evaluated and documented.

Gesetzliche und andere Anforderungen

Die gesetzlichen und anderen Anforderungen werden erfasst und die Einhaltung überwacht. Hierzu führt die Drägerwerk AG Register über:

Legal and Other Requirements

The legal and other requirements are identified and compliance with these requirements is monitored.
To this end, Drägerwerk AG keeps registers of:

- für das Unternehmen geltende Rechtsvorschriften
- behördliche Anordnungen und Auflagen gemäß Genehmigungsbescheiden

Anforderungen, die über gesetzliche Regelungen und behördliche Auflagen hinausgehen, werden z.B. in umweltbezogenen Standards und Arbeitsanweisungen geregelt.

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- legal regulations applicable to the company
- official instructions and requirements in accordance with approval documents

Requirements which exceed legal regulations and official requirements are regulated in, for example, environment-related standards and working instructions.

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Umweltziele und –programme

Die Dräger Safety AG & Co. KGaA ermittelt Umweltziele und führt Programme zur Erfüllung von Einzelzielsetzungen ein, die im Einklang mit der Umweltpolitik stehen.

Environmental Objectives and Programmes

Dräger Safety AG & Co. KG aA establishes environmental objectives and introduces programmes to meet individual objectives which are consistent with the environmental policy.

Umweltmanagement System Bewertung

Das Umweltmanagement System der Dräger Safety AG & Co. KgaA wird regelmäßig bewertet. Basis hierfür ist der Umweltbericht des Beauftragten der obersten Leitung. Wichtige Fragestellungen sind dabei die Notwendigkeit der Umsetzung grundlegender Empfehlungen aus internen Audits, sowie die Betrachtung der Angemessenheit der Umweltpolitik bzw. genereller Zielsetzungen aufgrund neuer Entwicklungen oder organisatorischer Änderungen im Unternehmen.

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Environmental Management System Review

The environmental management system of Dräger Safety AG & Co. KGaA is regularly reviewed on the basis of the management representative's environmental report. Important issues in this context are the need to implement basic recommendations from internal audits and an analysis of the appropriateness of the environmental policy and/or general objectives in the face of new developments or organizational changes within the company.

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6 Management von Ressourcen

Die erforderlichen Ressourcen werden jährlich im Rahmen des Planungsprozesses ermittelt und bereitgestellt.
Die Planung basiert auf dem Ist- Stand und der aktuellen Strategie. Sie umfaßt Personal- und Sachkosten, Investitionen, Abschreibungen, Entwicklungsaufwand etc. und mündet im Budgetplan der Kostenstellen.
Die Verdichtung wird im Management Report dem Vorstand präsentiert und von diesem genehmigt.
Hinter den Einzelplanungen, wie Personal, Entwicklung oder Infrastruktur liegen ebenfalls definierte Prozesse.
Der Qualifikationsbedarf der Mitarbeiter wird zum einen im Abgleich mit den Tätigkeitsbeschreibungen und zum anderen in den Mitarbeitergesprächen ermittelt und mit definierten Maßnahmen abgedeckt.

6 Resource Management

The resources needed are determined and provided within the framework of the annual planning process.
Planning is based on the actual situation and current strategy. It covers personnel and material costs, investments, write-offs, R&D spending etc. and forms the basis for the budget plan of the cost centres. A summary of the costs is presented to and approved by the Executive Board in the Management Report.
The individual plans concerning personnel, development or infrastructure are likewise based on defined processes.
The need for staff training is determined both by analysing job descriptions and in the framework of the employee feedback meetings; the training requirements are addressed with defined actions.

QualitätsManagement - Handbuch
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7 Produktrealisierung

7.1 Planung der Produktrealisierung

Die Realisierung eines neuen Produktes läuft geplant ab.
Die Planung gliedert sich in drei Phasen:

- **Ideenphase**
- **Definitionsphase**
- **Realisierungsphase**

Im Rahmen dieser Planung werden *mindestens:*
Produktziele, Produktstrategie, Kundenanforderungen, Wirtschaftlichkeit, Risiken, Produktions- und Servicekonzept berücksichtigt.

Das Ergebnis der Ideenphase ist die Entscheidung, ob in die Definitionsphase eingetreten wird. In diesem Fall entsteht als Dokumentation ein Projektauftrag.
Die Definitionsphase umfaßt die detaillierte Planung des Projektes und endet mit einem Projekt Review, welches die Entscheidungsbasis für den Eintritt in die Realisierungsphase liefert. Die Qualitätsziele und Anforderungen an das Produkt sowie die erforderlichen Verifizierungs-, Validierungs-, Überwachungs- und Prüfschritte werden in Lastenheft und Pflichtenheft dokumentiert. Berücksichtigt werden hierbei außer den Kundenanforderungen einschlägige Normen und gesetzliche Auflagen (insbesondere Anforderungen aus EG-Richtlinien wie "Persönliche Schutzausrüstungen" und "Ex-Schutz"). Die Anforderungen einer nachhaltigen Entwicklung wird durch die Verpflichtung zur umweltgerechten Konstruktion umgesetzt. Die Schonung der Umwelt ist schon bei der Planung eines neuen Produktes ein wichtiger Aspekt, zentrale Punkte sind Vermeidung umweltbelastender Materialien, umweltschonende Fertigungsprozesse, recyclingfreundliche Konstruktion und Rücknahmekonzept.

7 Product Realization

7.1 Planning of Product Realization

The realization of a new product is a planned process.
Planning takes place in three phases:

- **Ideas phase**
- **Definition phase**
- **Realization phase**

The planning phase takes into account at least:
product objectives, product strategy, customer requirements, economic efficiency, risks, production and service concept.

The result of the ideas phase is the decision whether to proceed to the definition phase. In this case, a project order is documentated.

The definition phase includes a more detailed plan of the project and ends with a project review which forms the decision-making basis for proceeding to the realization phase. The quality objectives and requirements for the product, as well as the necessary verification, validation, monitoring, inspection and test activities, are documented in the customer requirements specification and technical requirements specification. Apart from customer requirements, relevant standards and legal requirements are taken into account during this phase (in particular requirements from EC Directives such as "Personal Protective Equipment" and "Explosion Prevention"). The requirements for sustainable development will be met through the company's voluntary commitment to environmentally-compatible design and construction. Protection of the environment is an important aspect even when planning a new product: central issues are the avoidance of polluting materials, environmentally friendly production processes, recyclable design and product return concepts.

In der Realisierungsphase wird unter fixierten Projekt- und Marktdaten die konkrete Umsetzung der Planung betrieben und der Fortschritt in festgelegten Reviews kontrolliert.

In the realization phase, frozen project and market data are used for the concrete implementation of the plan and progress is monitored in specified reviews.

Der gesamte Projektverlauf wird in der Projektakte dokumentiert.
Der benannte Projektleiter ist verantwortlich für die Einhaltung der Projektziele mit den geplanten Ressourcen im vorgesehenen Zeit- und Kostenrahmen. Zuständig für Einzelaufgaben ist das Projektteam bzw. eingebundene Fachbereiche.

The course of the entire project is documented in the project file.
The appointed project manager is responsible for achieving the project objectives with the planned resources within the intended timescale and without exceeding the budgeted costs. The project team and/or participating specialist departments are responsible for individual tasks.

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7.2 Kundenbezogene Prozesse

Für das zu realisierende Produkt werden alle Anforderungen
- vom Kunden,
- die sich aus dem beabsichtigten Gebrauch ergeben,
- aus gesetzlichen und behördlichen Vorgaben
- aus Umweltschutzaspekten

sowie aus internen Vorgaben ermittelt, in einem Lastenheft dokumentiert und nach erfolgter Bewertung in ein Pflichtenheft aufgenommen.
Hilfsmittel hierfür ist z.B. QFD-Analyse

Verpflichtende Kundenanforderungen werden vor Angebotsabgabe oder Vertragsannahme bewertet, um sicherzustellen, daß die Festlegungen erfüllbar sind.

Änderungen an Produktanforderungen bewirken eine Neubewertung und werden entsprechend der Abläufe für neue Produkte bearbeitet.

Die Kommunikation mit Kunden wird außer über den persönlichen Kontakt durch Vertriebs- und Serviceorganisation, z. B. über eine eigene Kundenzeitung (Drägerheft), intensive Nutzung des Internet und Bekanntgabe von spezifischen Telefonnummern / e-Mail Adressen in Produktinformationen aktiv betrieben.
Alle Produktinformationen durchlaufen vor Veröffentlichung einen Prüf- und Freigabeprozeß.

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7.2 Customer - Related Processes

For the product to be realized, all requirements
- from customers,
- resulting from the intended use,
- from laws and regulations
- from environmental protection aspects

and from internal regulations will be determined, documented in a customer requirements specification and, after evaluation, included in a technical requirements specification.
A possible aid in this context is the QFD analysis.

Binding customer requirements are evaluated prior to submission of tender or acceptance of contract to ensure that the requirements can be met.

Changed product requirements trigger a repeat evaluation and are treated in the same way as processes for new products.

Active communication with customers takes place not only via personal contact between customers and the sales and service organization, but also through, for example, the company's own customer journal (Dräger Review), intensive use of the internet and publication of specific telephone numbers / e-mail addresses in product information brochures.
Prior to publication, all product information undergoes an inspection and release process.
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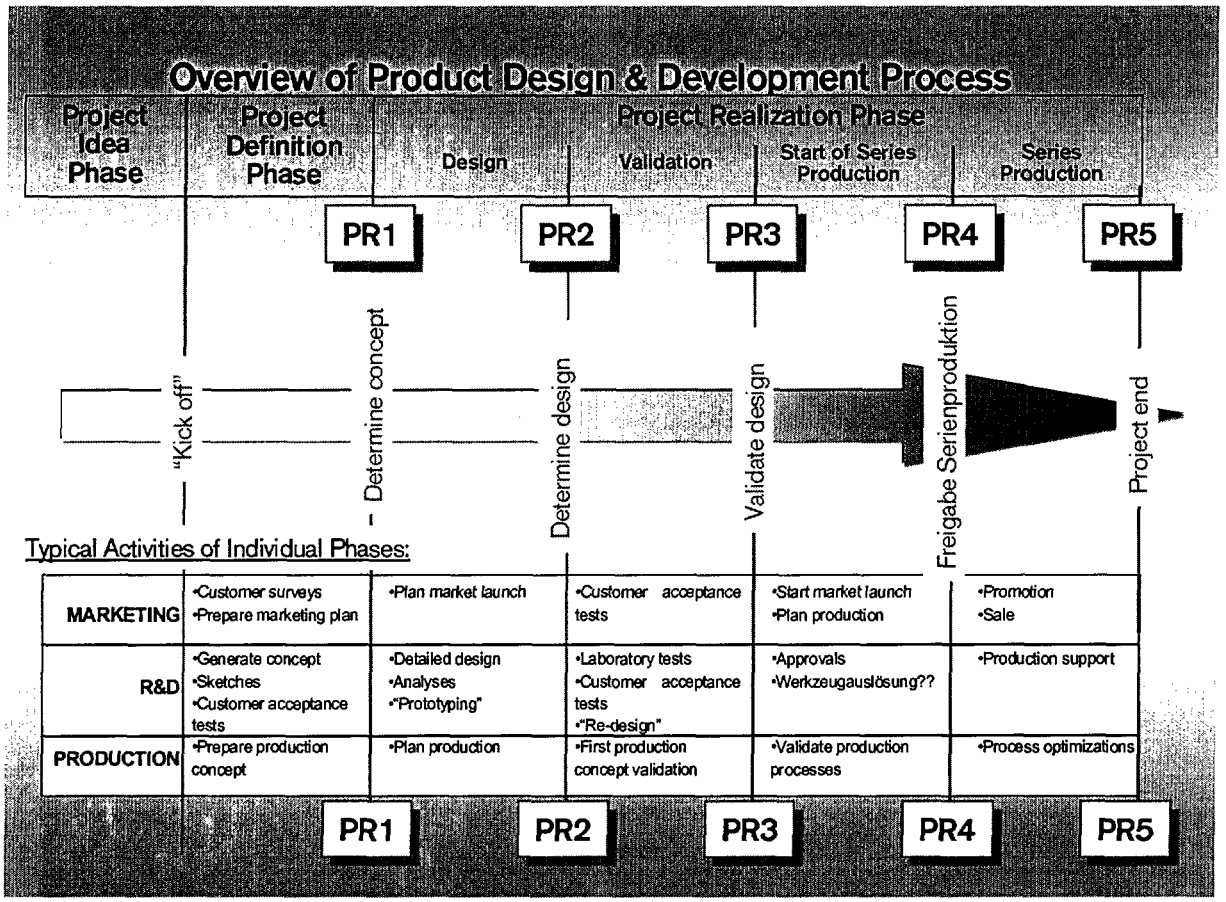
7.3 Entwicklung / Design and Development

Die Neuentwicklung und Modifikation von Produkten wird geplant und gelenkt.
Sie läuft in festgelegten Phasen ab.
The design and development of new products and the modification of existing products is a planned and controlled process. It consists of a number of defined phases.



Der benannte Projektleiter ist verantwortlich für die Einhaltung der Projektziele mit den geplanten Ressourcen im geplanten Zeit- und Kostenrahmen.
Er ist zuständig für die Planung, Koordinierung und Überwachung des gesamten Entwicklungsvorhabens sowie das Führen und Pflegen der Projektdokumentation. Zuständig für die Einzelaufgaben sind das Projektteam bzw. die eingebundenen Fachbereiche.
Jede Designphase wird mit einem Projekt Review abgeschlossen. Anhand der dazu vorgeschriebenen Bewertungslisten wird der tatsächlich erreichte Projektstand überprüft und dokumentiert. Gegebenenfalls wird die Planung aktualisiert.

The appointed project manager is responsible for achieving the project objectives with the planned resources within the intended timescale and without exceeding the budgeted costs.
He is responsible for planning, coordinating and supervising the entire design and development project and for maintaining and updating the project documentation. The project team and/or participating specialist departments are responsible for individual tasks.
Each design phase ends with a project review. The actual project status achieved is reviewed and documented on the basis of review lists specifically designed for this purpose. If necessary, plans are updated.

Die Freigabe der einzelnen Designphasen durch benannte Führungskräfte stellt sicher, dass die Designvorgaben mit dem erreichten Entwicklungsstand übereinstimmen. Bei positiver Bewertung der Arbeitsergebnisse erfolgt die Freigabe des nächsten Projektabschnitts. Die Dokumentation erfolgt in der Projektakte und stellt dadurch die Nachvollziehbarkeit aller Designphasen sicher. Der Projektleiter legt bei Abweichungen Maßnahmen fest, die das Erreichen der festgelegten Ziele gewährleisten.

Release of the individual design phases by appointed managers ensures that the actual design and development status is consistent with the design input requirements. If the review of the outputs is positive, the next stage of the project is released. Documentation is provided in the form of the project file, ensuring the traceability of all design phases. In the event of deviations, the project manager defines actions to ensure that the specified objectives are achieved.

In der Designphase werden Labortests und Tests mit Felderprobungsgeräten sowie Fertigungserprobungen geplant durchgeführt. Mit den Produkttests verifizieren wir in den jeweiligen Projektabschnitten die Funktionalität, Leistungsfähigkeit, Umweltverträglichkeit, Zuverlässigkeit und Sicherheit des Produktes.
Die Testergebnisse werden ausgewertet und den Forderungen aus dem Lastenheft gegenübergestellt. Die Ergebnisse und notwendigen Maßnahmen werden aufgezeichnet.

In the design phase, laboratory tests and tests with field trial units and production prototypes are planned and conducted. We use the product tests to verify the product's functionality, performance, environmental compatibility, reliability and safety at each stage of the project.
The test results are evaluated and set against the requirements from the customer requirements specification. The results and necessary actions are recorded.

Als Ergebnis des Entwicklungsprozesses müssen die erforderlichen Informationen und Anforderungen für Beschaffung, Produktion und Dienstleistungserbringung bereitstehen sowie Annahmekriterien für das Produkt und die Merkmale für den sicheren und bestimmungsgemäßen Gebrauch festgelegt sein.

Design and development outputs must provide the necessary information and requirements for purchasing, production and for service provision and specify product acceptance criteria and the characteristics of the product that are essential for its safe and proper use.

Designänderungen
Alle Designänderungen und -modifikationen werden vor ihrer Einführung von den verschiedenen Fachbereichen identifiziert, geprüft, freigegeben und dokumentiert. Umfangreiche Designänderungen werden wie Neuentwicklungen behandelt.

Design Changes
All design changes and modifications are identified, tested, released and documented by the various specialist departments before implementation. Major design changes are treated as new developments.

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7.4 Beschaffung

Mit einer geregelten Beschaffung von Produkten und Dienstleistungen wird sichergestellt, daß die festgelegten Forderungen an Qualität, die Beachtung der Umweltaspekte und die gesetzlichen Forderungen zur Arbeitssicherheit eingehalten werden.

Für den geregelten Ablauf des Beschaffungsvorganges ist der Einkauf verantwortlich. Er koordiniert die erforderlichen Maßnahmen zur Sicherung der Qualität von Zulieferungen und Dienstleistungen.
Die Prüfung und die Entscheidung über die Freigabe der beschafften Produkte und Dienstleistungen erfolgt durch die von dem zuständigen Qualitätskoordinator ernannten Berechtigten.

Mit der systematischen Auswahl geeigneter Lieferanten, der Vorgabe eindeutiger und vollständiger Beschaffungsunterlagen sowie der Beurteilung der Qualität von Zulieferungen und der Einleitung entsprechender Verbesserungsmaßnahmen schaffen wir die Voraussetzung dafür, die Qualität der Zulieferungen gemeinsam mit den Lieferanten auf der Basis der vereinbarten Forderungen zu sichern.
Wesentliche Punkte im Beschaffungsprozeß sind:

- Auswahl geeigneter Lieferanten
- Vergabe von Lieferantenzulassungen
- Qualitätsvereinbarungen mit dem Lieferanten
- Prüfung der beschafften Produkte und Dienstleistungen
- Durchführung von Lieferantenaudits
- Bewertung der Qualitätsfähigkeit von Lieferanten
- Bewertung der Umweltleistung von Lieferanten
- Vorgaben für die Beschaffung umweltverträglicher Materialien und Leistungen

7.4 Purchasing

Regulating the purchase of products and services ensures compliance with the defined quality requirements, environmental aspects and statutory occupational safety regulations.

The purchasing department is responsible for regulating the purchasing process. It coordinates the activities necessary to ensure the quality of purchased products and services.
The competent quality coordinator appoints staff authorized to inspect and decide whether to release the purchased products and services.

By systematically selecting suitable suppliers, providing clear and complete purchasing documents and evaluating the quality of supplies and introducing appropriate improvement measures, we create the basis for ensuring, together with the suppliers, the quality of purchased products and services on the basis of the agreed requirements.
The main stages of the purchasing process are as follows:

- Selection of suitable suppliers
- Allocation of supplier approvals
- Quality agreements with suppliers
- Inspection of purchased products and services
- Performance of supplier audits
- Evaluation of the quality capability of suppliers
- Evaluation of the environmental performance of suppliers
- Requirements for the purchase of environmentally compatible materials and services

Art und Umfang der Qualitätssicherungsschritte werden in der Entwicklungsphase geplant, erprobt und anschließend umgesetzt.
Die systematische Bewertung der ausgewählten Lieferanten, unter Einbeziehung der von der Dräger Safety verfolgten Qualitäts- und Umweltpolitik, bildet die Grundlage einer vertrauensvollen und guten Zusammenarbeit mit dem Lieferanten.

Jede eingehende Lieferung wird einer Prüfung nach produktspezifischen Prüfanweisungen unterzogen. Die Lieferung darf bis zur Freigabe durch den Berechtigten nicht vereinnahmt und in den Materialfluß eingeschleust werden.

Das Erfassen und Bewerten der Prüfergebnisse bilden die Grundlage für die Aussagefähigkeit über die Lieferantenqualität und dienen gegebenenfalls zur Einleitung gezielter Qualitätsverbesserungsmaßnahmen beim Lieferanten.
Werden in einer Lieferung fehlerhafte Produkte festgestellt, erhält der Lieferant einen Qualitätsmangelbericht (QMB) mit der Aufforderung zur Stellungnahme über die eingeleiteten Korrektur- und Verbesserungsmaßnahmen.

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The type and scope of quality assurance measures are planned, tested and then implemented in the design and development phase.
The systematic evaluation of the selected suppliers, taking into consideration Dräger Safety's quality and environmental policy, establishes the framework for good cooperation with the supplier based on mutual trust.

All incoming deliveries are subjected to inspection on the basis of product-specific test procedures. Until released by the authorized member of staff, the delivery cannot be accepted and incorporated into the material flow.

Recording and evaluating the results of the inspection forms the basis for determining the supplier quality and is also used, if necessary, to initiate targeted quality improvement measures at the supplier's premises.

If nonconforming products are discovered in a particular delivery, the supplier will be issued a Nonconformance Report and required to comment on the corrective action and improvement measures initiated.

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7.5 Produktion und Dienstleistungs-erbringung

Die Qualität der Produkte wird durch geplante und beherrschte Produktionsprozesse sichergestellt, Umweltaspekte werden schon während der Planung berücksichtigt.

Die Planung und Festlegung der Produktionsprozesse ist Bestandteil der Designphasen; die Verfügbarkeit aller erforderlichen Spezifikationen, Arbeitsanweisungen, Ausrüstung, Überwachungs- und Meßmittel, sowie deren Anwendung bzw. Umsetzung wird im Produktionsprozeß sichergestellt.
Umweltrelevante Fertigungsprozesse werden gemäß interner Regelungen überwacht und kontrolliert.
Die Leistungsfähigkeit der Fertigungsprozesse wird untersucht, - diese Daten bilden die Grundlage für Auswahl und Überwachung.
Fertigungsprozesse werden je nach Eignung zur Merkmalserfüllung einer Prozeßklasse zugeordnet, die in Kombination mit Merkmalsklassen zu definierten Fertigungs- und Qualitätssicherungsmaßnahmen führt.
Die Spezifikationskonformität der Produkte und Dienstleistungen wird durch Überwachung und Messung verifiziert. Anderenfalls kommen validierte Produktionsprozesse zur Anwendung.

Gefertigte und gelieferte Produkte werden so gekennzeichnet, daß eine eindeutige Zuordnung zu einem dokumentierten technischen Stand sichergestellt ist. Die eindeutige und vollständige Beschreibung des Produktes erfolgt in Zeichnungen und Stücklisten, sowie in weiteren zugeordneten Dokumenten, die in der Zeichnung oder der Stückliste aufgeführt sind.
Die Rückverfolgbarkeit einzelner Produkte zum Kunden ist in einem Dräger Safety Standard festgelegt. Die Sachnummern und Fabrikations-Nummern bestimmter Geräte werden dadurch dem Kunden zugeordnet.

7.5 Production and Service Provision

The quality of products is ensured by means of planned and controlled production processes. Environmental aspects are taken into account at the planning stage.

Planning and defining the production processes forms an integral part of the design phases; the availability of all necessary specifications, work instructions, equipment, monitoring and measuring devices, as well as their application or implementation, is ensured by the production process.

Production processes with environmental relevance are monitored and controlled in accordance with internal regulations.
The efficiency of the production processes is examined: this data forms the basis for selection and monitoring.
Production processes are assigned to a process class according to their suitability for providing a particular characteristic. This process class, in combination with characteristic classes, leads to defined production and quality assurance measures.
The conformity of the products and services to the specifications is verified by means of monitoring and measuring. In other cases, validated production processes are used.

Manufactured and delivered products are identified such that they can be clearly assigned to a documented technical status. The product is uniquely and completely described in drawings and parts lists, and in other related documents listed in the drawing or parts list.
The traceability of individual products to the customer is specified in a Dräger Safety Standard. The part numbers and serial numbers of certain devices are thereby assigned to the customer.

Die Kennzeichnung von Gefahrstoffen und gefährlichen Gütern erfolgt gemäß den nationalen und internationalen Vorschriften, sowie den Standards des Dräger Konzerns. Die Kennzeichnung von Anlagen und Anlagenteilen erfolgt gemäß den nationalen Gesetzen und zugehörigen Verordnungen sowie den nationalen Vorschriften der Arbeitssicherheit.

Identification of hazardous substances and dangerous goods takes place in accordance with national and international regulations and the standards of the Dräger Group. Identification of plants and facilities takes place in accordance with national laws and the applicable regulations, and national occupational safety regulations.

Eigentum von Kunden im Lenkungsbereich der Dräger Safety wird einzelfallbezogen geregelt: der Vertrieb trifft mit dem Auftraggeber vertragliche Vereinbarungen über technischen Stand, Behandlung, Dokumentation sowie das Abrufverfahren. Vom Kunden beigestellte Produkte werden analog zu Einkaufsteilen in die Fertigungsunterlagen aufgenommen und unterliegen den gültigen Qualitätssicherungsstandards. Die technischen Daten, Schnittstellen zu Produkten der Dräger Safety und ggf. Prüfmerkmale werden in der Zeichnung festgelegt. Die weitere Verwendung erfolgt nach den Zeichnungsvorgaben und den gültigen Regeln für Transport, Aufbewahrung und Handhabung. Fehler die während der Fertigung erkannt werden, sind dem Kunden mitzuteilen und das weitere Vorgehen ist durch den Vertrieb abzustimmen.

Customer property under the control of Dräger Safety is dealt with on a case-by-case basis: the sales department enters into contractual agreements with the customer concerning technical status, treatment, documentation and call-off orders. Products provided by the customer are included in the production documents in the same way as purchased parts, and are subject to the applicable quality assurance standards. The technical data, interfaces with products of Dräger Safety and, if applicable, test characteristics, are defined in the drawing. Their further use is determined by the requirements set out in the drawing and the valid regulations for transport, storage and handling. Nonconformities which are discovered during production must be reported to the customer and the further procedure discussed and agreed with the sales department.

Zur Vermeidung von Produktbeschädigungen und -beeinträchtigungen, sowie zur Sicherstellung des sorgfältigen Umganges mit Produkten, sind Festlegungen über den Umgang und Mittel für die Handhabung Bestandteil der fertigungsbegleitenden Papiere.
Die in nationalen Gesetzen und Vorschriften festgelegten Forderungen zum Umgang mit Gefahrstoffen und gefährlichen Gütern werden angewendet.
Getrennte Lagerbereiche sowie Zwischen- und Bereitstellungslager sind auf die Anforderungen der zu lagernden Produkte abgestimmt. Die Warenannahme, Lieferung an Läger sowie Entnahme aus Lägern ist in Arbeitsanweisungen für das Lagerwesen festgelegt.

To avoid product damage or impairment, and to ensure that products are treated with due care, requirements concerning their treatment and handling equipment form an integral part of the production-related documentation.
The requirements defined in national laws and regulations regarding the handling of hazardous substances and dangerous goods are applied.
Separate storage areas and intermediate and standby storage facilities are designed to meet the requirements of the products to be stored therein. Work instructions for the warehousing department exist to regulate the acceptance of goods, delivery into stock and removal from stock.

Der Zustand der Produkte wird überall dort, wo es zur Sicherung der Qualität erforderlich ist (z.B. bei Produkten, die der Altersüberwachung unterliegen) in festgelegten Abständen oder zu festgelegten Zeitpunkten überprüft.
Bei der Lagerung von Gefahrstoffen oder gefährlichen Gütern werden die nationalen Sicherheitsbestimmungen (z.B. getrennte Lagerung, Sicherheitsabstände) eingehalten.
Durch geeignete und gleichzeitig umweltfreundliche Verpackungen werden die Produkte vor Beschädigungen und Beeinträchtigungen während der Lagerung, des Transportes und des Versandes geschützt.
Die Verpackung wird zusammen mit dem Produkt entwickelt, bei Bedarf nach Kundenvorgaben qualifiziert und als Bestandteil der Produktstückliste mit einer eigenen Verpackungszeichnung konstruktiv festgelegt. Der Hinweis auf die zu verwendende Verpackung ist Bestandteil des Beschaffungspaketes bei Zulieferteilen.
Für den Transport von gefährlichen Gütern werden die Verpackungen gemäß den nationalen Vorschriften gekennzeichnet, die festgelegten Transportbedingungen angewendet und die vorgeschriebenen Transportpapiere der Lieferung beigefügt.
Die Produkterhaltung wird durch geeignete Lagerbedingungen (Temperatur, Feuchte usw.) sichergestellt. Bei Bedarf werden innerbetriebliche Transport- und Lagerverpackungen festgelegt.

(Abschnitt 9)

The condition of products is checked at defined intervals or at defined times wherever this is necessary for the purposes of quality assurance (e.g. in the case of products subject to age control).

National safety regulations (e.g. separate storage, safe distances) are observed when hazardous substances or dangerous goods are stored.
Products are protected by appropriate, environmentally-friendly packaging against damage and impairment during storage, transport and shipping.

The packaging is developed at the same time as the product, designed upon request to customer specification and its design specified in its own packaging drawing and included on the product's part list. The reference to the packaging to be used forms part of the purchasing package in the case of supplied parts.
For the transport of dangerous goods, packaging is labelled in accordance with national regulations, the specified transport conditions applied and the delivery's necessary transport documents attached.
Preservation of the product is ensured by maintaining suitable storage conditions (temperature, humidity etc.). Upon request, internal company transport and storage packaging is defined.

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7.6 Lenkung von Überwachungs- und Meßmitteln

Der Nachweis der Produktkonformität mit den festgelegten Anforderungen wird durch geeignete Überwachung und Messungen gewährleistet.
Die erforderlichen Überwachungs- und Meßmittel werden während der Entwicklungsphase eines Produktes auch unter den Gesichtspunkten des Umweltschutzes geplant, ihr Entwicklungsstand wird in den Projektreviews zur Produktentwicklung abgefragt. Sie beginnt mit der Festlegung der Spezifikation, führt dann zur Realisierung der Prüfmittel, deren Erfassung und Freigabe, bis hin zur Kalibrierung und Wartung.
Alle für die Qualitätsprüfung eingesetzten Prüfmittel werden von den festgelegten Kalibrierstellen registriert, regelmäßig kalibriert und gekennzeichnet. Dies gilt auch für Prüfmittel, die der Überwachung umweltrelevanter Anlagen dienen. Die Kalibrierergebnisse werden bewertet und aufgezeichnet. Bei Nichterfüllung der Anforderungen werden geeignete Maßnahmen bezüglich der Prüfmittel und ggfs. betroffener Produkte ergriffen.
Zur Überwachung und Messung festgelegter Anforderungen vorgesehene Software wird validiert.

(Abschnitt 9)

7.6 Control of Monitoring and Measuring Devices

Evidence of the product's conformity to determined requirements is provided by suitable monitoring and measurement.
Planning of the necessary monitoring and measuring devices takes place during the product's design and development phase, also taking into account aspects of environmental protection. The development status of the monitoring and measuring devices is checked in the product development project reviews. The development of test equipment begins with a determination of its specification, continues with its realization, registration and release, and ends with calibration and maintenance.
All equipment used for quality testing is registered, regularly calibrated and identified by the specified calibration bodies. This also applies to test equipment used to monitor plants and facilities with environmental relevance. The calibration results are reviewed and recorded. If the requirements are not met, suitable action is taken with regard to the test equipment and any products affected.
Software used to monitor and measure determined requirements is validated.

(Section 9)

8 Messung, Analyse und Verbesserung

8.1 Grundsätzliche Vorgehensweise

Die Aktivitäten bezüglich Überwachung und Messung zur Sicherstellung der Konformität von Produkten sind definiert.
Es gibt ebenfalls definierte Aktivitäten zur kontinuierlichen Verbesserung unter Nutzung zielführender Methoden einschließlich statistischer Verfahren.

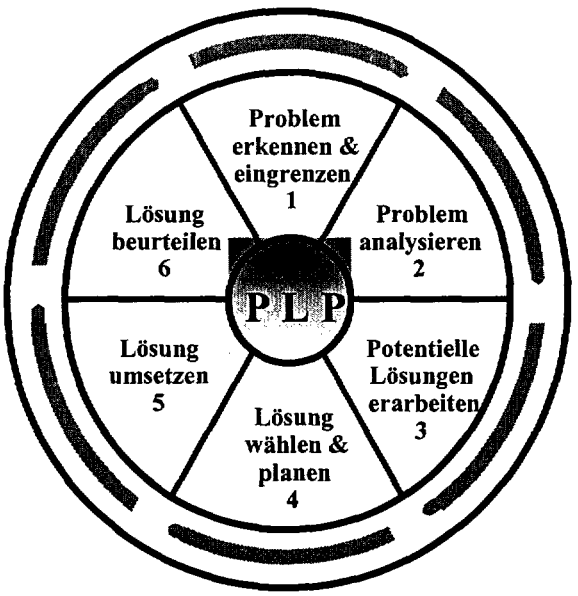
Generell wird zur systematischen Bearbeitung erkannter Nichtkonformitäten der Problem-Lösungs-Prozess eingesetzt.

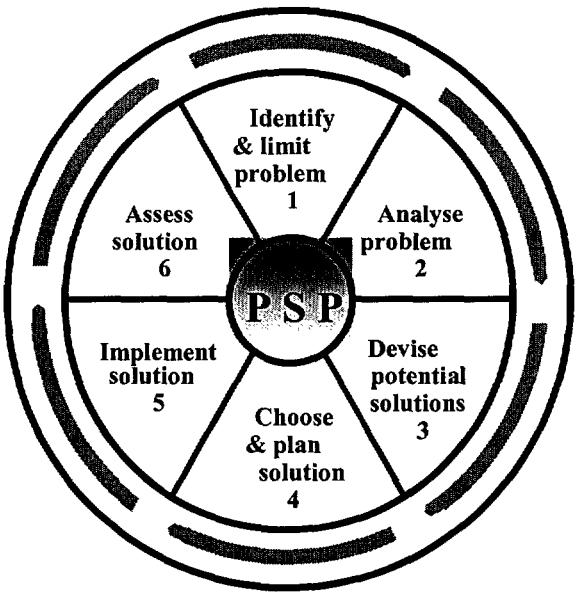
8 Measurement, Analysis and Improvement

8.1 Fundamental Procedure

The monitoring and measurement activities to ensure product conformity are defined.
Defined activities likewise exist to ensure continual improvement, using targeted methods, including statistical techniques.

In general, the problem-solving process is used to systematically tackle recognized non-conformities.





8.2 Überwachung und Messung

8.2.1 Kundenzufriedenheit

Der Grad der Erfüllung der Kundenanforderungen ist ein wesentliches Maß für die Leistung des Qualitätsmanagementsystems.
Zur Erlangung und Überwachung dieser Information werden außer der systematischen Erfassung und Analyse der Reklamationen regelmäßige Kundenzufriedenheitsanalysen in Form von Umfragen durchgeführt.
Diese Umfragen werden jährlich durchgeführt, die Ergebnisse ausgewertet und den internationalen Entscheiderkreisen präsentiert.
Die abgeleiteten Maßnahmen haben Einfluß auf die Marketing- Pläne und alle betroffenen Prozesse.

(Abschnitt 9)

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

The degree to which customer requirements are met is an important measurement of the performance of the quality management system.
To obtain and monitor this information, regular customer satisfaction analyses are carried out in the form of surveys, and complaints are systematically registered and analysed.

These surveys are conducted annually, the results analysed and presented to the international decision-making groups.
The actions determined on the basis of the results have an influence on the marketing plans and all affected processes.

(Section 9)

8.2.2 Internes Audit

Um zu ermitteln, ob das Qualitäts- und Umweltmanagement die internen Vorgaben und die externen Anforderungen erfüllt, verwirklicht und mit dem Ziel der kontinuierlichen Verbesserung aufrechterhält, werden interne Audits geplant und durchgeführt.
Interne Qualitätsaudits werden von der Unternehmensleitung als wirksames Führungs- und Steuerungselement zur regelmäßigen Überprüfung der Anwendung, Wirksamkeit, Zweckmäßigkeit und Verbesserungsmöglichkeit des Managementsystems eingesetzt.
Verantwortlichkeiten und Anforderungen sind in einem dokumentierten Standard festgelegt.
Die internen Qualitätsaudits werden von ausgebildeten Auditoren nach den geltenden Dräger Safety Vorgaben durchgeführt. Die Auditoren dürfen keine direkte Verantwortung in dem zu auditierenden Bereich haben. Die notwendige Fachkompetenz wird durch eine entsprechende Zusammensetzung der Auditorenteams gewährleistet.

Die Festlegung der Auditthemen sowie eine systematische Planung der Audits ist Aufgabe der Leitung Qualität, Umwelt, Standards. Sie erfolgt in Abstimmung mit der Geschäftsleitung unter Berücksichtigung der Kundenforderungen, Standards und Anweisungen.

Nach jedem Audit wird ein Auditbericht erstellt und sowohl der Leitung der auditierten Bereiche, der BU- Leitung als auch der Leitung Qualität, Umwelt, Standards zur Kenntnis gebracht. Notwendige Verbesserungen werden je nach Wichtung als Problemlösungsprozeß oder über Maßnahmenvorgaben und Umsetzung in der jeweiligen Business Unit eingeführt.
Eine Zusammenfassung der Auditergebnisse wird im Rahmen des Managementreviews der Geschäftsleitung und den Business Units vorgestellt.

(Abschnitt 9)

8.2.2 Internal Audit

Internal audits are planned and conducted to determine whether the quality and environmental management systems meet the internal and external requirements and are implemented and maintained with the goal of continual improvement.

Internal quality audits are used by management as an effective guiding and control element to regularly check the application, effectiveness and usefulness of and possible improvements to the management system.
Responsibilities and requirements are defined in a documented standard.

The internal quality audits are conducted by trained auditors in accordance with the applicable Dräger Safety regulations. The auditors must have no direct responsibility in the area to be audited. The audit team is composed such as to ensure that the necessary specialist skills and knowledge are available.

The head of Quality, Environment, Standards, in consultation with top management, is responsible for determining the audit topics and systematically planning the audits, taking customer requirements, standards and instructions into account.

An audit report is compiled after each audit and presented to the managers of the audited areas, the BU manager and the head of Quality, Environment, Standards. Depending on their priority, necessary improvements are initiated through either a problem-solving process or specified action and implementation in the respective business unit.
A summary of the audit results is presented to management and the business units during the course of the management review.

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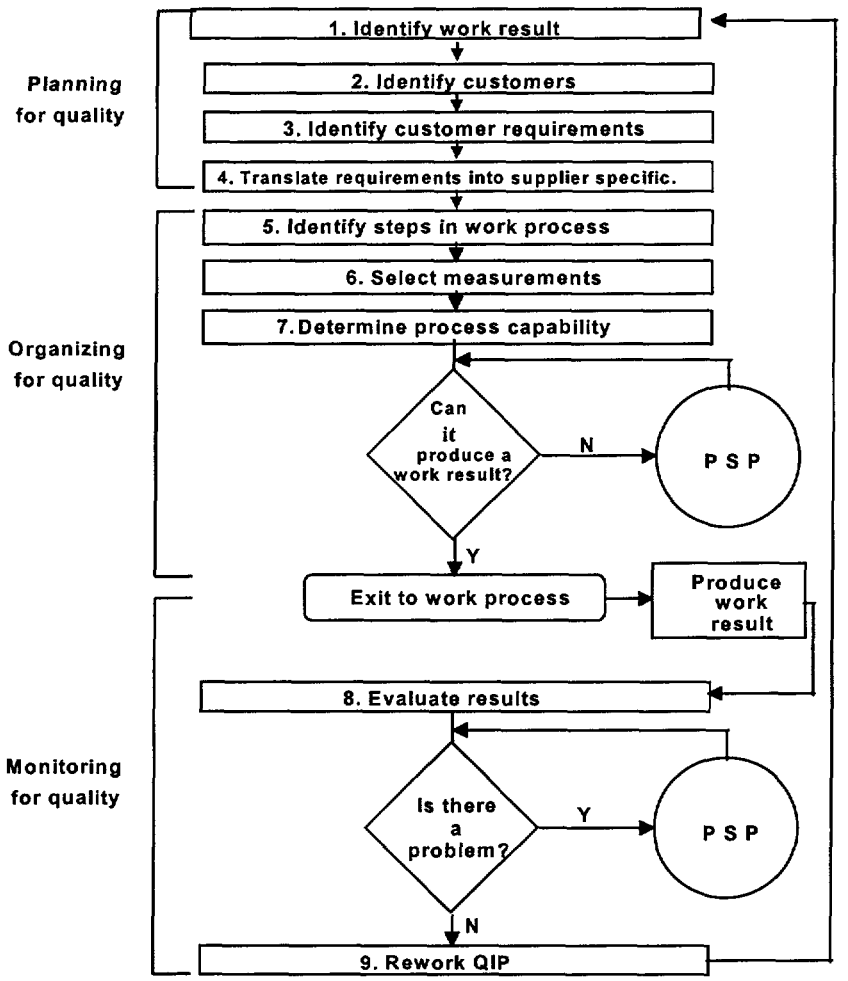
8.2.3 Überwachung und Messung von Prozessen

Der Standardablauf bei der Einführung neuer Prozesse bzw. bei umfangreichen Änderungen von Prozessen ist der "Qualitäts-Verbesserungs-Prozess" (QVP).

8.2.3 Monitoring and Measurement of Processes

The standard procedure for the introduction of new processes and significant changes to existing processes is the "Quality Improvement Process" (QIP).



Die Überwachung der wesentlichen Prozesse erfolgt mittels Kennzahlen.

Operating figures are used to monitor the main processes.

8.2.4 Überwachung und Messung des Produkts

Die während des Entwicklungsprozesses festgelegten Produktanforderungen werden in den verschiedenen Phasen der Produktrealisierung überwacht und ihre Erfüllung verifiziert.
Die Planung und Durchführung der Überwachungstätigkeiten erfolgt durch benannte, qualifizierte Mitarbeiter, die Freigabe erfolgt dokumentiert nach zufriedenstellender Durchführung o.a. Tätigkeiten ebenfalls durch benannte qualifizierte Mitarbeiter.
Die Vorgaben sind in Form von Prüfanweisungen für Wareneingangsprüfungen, Prüfungen in der Fertigung und nach Reparatur bzw. Instandhaltung festgelegt.

(Abschnitt 9)

8.2.4 Monitoring and Measurement of Product

The product requirements determined during the design and development process are monitored in the various stages of the product realization process to verify that they have been met.
Planning and performance of monitoring activities is carried out by appointed, qualified staff. Once the monitoring activities have been carried out satisfactorily, they are released and the release documented by appointed, qualified staff.
The requirements are specified in the form of inspection instructions for incoming goods inspections, tests in production and after repair or maintenance.

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8.3 Lenkung fehlerhafter Produkte

Die Lenkung fehlerhafter Produkte ist in einem dokumentierten Standard festgelegt. Es wird sichergestellt, daß keine Produkte mit Fehlern oder Abweichungen von der Spezifikation verarbeitet, eingelagert oder ausgeliefert werden.

Jeder Bereich in dem fehlerhafte Produkte festgestellt werden ist für die Kennzeichnung und Aussonderung solcher Produkte verantwortlich. Mitarbeiter verschiedener Fachbereiche entscheiden ob fehlerhafte Produkte nachgearbeitet, mit einer Abweichungsfreigabe weiter genutzt oder verschrottet werden.

Nach der Ablieferung von Produkten und Leistungen an den Empfänger, ob zur weiteren Bearbeitung, zur Einlagerung oder zur Auslieferung, gilt folgender Grundsatz: Für den Empfänger muß durch einen Freigabestempel in den Auftragsdokumenten ersichtlich sein, daß diese Produkte und Leistungen von befugten Prüf- und Freigabeberechtigten Mitarbeitern einer Qualitätsprüfung unterzogen und als geeignet für die bestimmungsgemäße Verwendung beurteilt wurden. Fehlerhafte Produkte dürfen an den Empfänger nicht weitergeleitet werden. Produkte ohne Freigabevermerk werden vom Empfänger zurückgewiesen. Zulieferungen mit Abweichungen von der Zeichnung oder von den Beschaffungsspezifikationen, sowie beanstandete Produkte aus der laufenden Fertigung werden, vom Mitarbeiter, der die Abweichung feststellt, gesperrt und verbleiben bis zur Klärung über die weitere Vorgehensweise in einem getrennten Sperrlager. Die beanstandeten Produkte werden als fehlerhaft gekennzeichnet. Ein externer Lieferant wird mit einem Qualitätsmangelbericht (QMB) informiert und zur Stellungnahme aufgefordert.
(Abschnitt 9)

8.3 Control of Nonconforming Products

The control of nonconforming products is defined in a documented standard. Steps are taken to ensure that no products with faults or which deviate from specifications are processed, stored or delivered.

Any department in which nonconforming products are discovered is responsible for identifying and rejecting such products. Staff from different specialist departments decide whether nonconforming products are to be reworked, approved for further use by a release for nonconforming products or scrapped.

Following the delivery of products or services to the recipient, regardless of whether for further processing, storage or delivery, the following basic principle applies: a release stamp in the order documents must clearly indicate to the recipient that the products or services have been subjected to a quality inspection by staff authorized to carry out inspection and release and have been deemed suitable for their intended purpose. Nonconforming products must not be passed on to the recipient. Products without release stamp are to be rejected by the recipient. Deliveries which do not conform to the drawing or purchase specifications and defective products from the production line are blocked by the member of staff who discovered the nonconformity and are kept in separate closed storage until it has been clarified what is to be done with them. Such products are identified as nonconforming. An external supplier is notified through a Nonconformance Report and requested to comment.

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8.4 Datenanalyse

Die Daten, die aus der Kundenzufriedenheitsanalyse (8.2.1), aus den Ermittlungen der Kundenanforderungen (7.2) , Lieferantenbewertungen (7.4) aus Prozeß- und Produktmessungen und gegebenenfalls weiteren Quellen gewonnen werden, werden erfaßt und analysiert.
Die Analysen sollen Aussagen über die Erreichung der geplanten Ziele sowie Trends und weitere Potentiale für Vorbeuge- und Verbesserungsmöglichkeiten eröffnen.

8.4 Analysis of Data

Data obtained from the customer satisfaction analysis (8.2.1), from a determination of the customer requirements (7.2), from supplier reviews (7.4), from process and product measurements and, if necessary, from other sources, are collected and analysed.
The analyses are designed to provide information about the achievement of the planned objectives and about trends and other opportunities for preventive action and improvement measures.

8.5 Verbesserung

8.5.1 Ständige Verbesserung

Die Qualitätspolitik, die daraus abgeleiteten Qualitätsziele, die Ergebnisse interner und externer Audits, die Ergebnisse der Datenanalysen, Korrektur- und Vorbeugungsmaßnahmen sowie die Managementbewertung werden eingesetzt, um die Wirksamkeit des Qualitätsmanagementsystems ständig zu verbessern.
Dies gilt auch für unser Umweltmanagementsystem. Wir leiten Maßnahmen zur Verbesserung unserer Umweltleistung aus unseren ermittelten relevanten Umweltkennzahlen wie z. B. den Daten aus dem Energiecontrolling und der Abfallstatistik, ab.

8.5 Improvement

8.5.1 Continual Improvement

The effectiveness of the quality management system is continually improved through the use of the quality policy, the quality objectives defined on the basis of the quality policy, the results of internal and external audits, the results of data analyses, corrective and preventive actions and the management review.

The same applies to our environmental management system. We determine action to improve our environmental performance on the basis of the relevant environmental ratios, e.g. data from energy controlling and waste statistics.

8.5.2 Korrekturmaßnahmen

Die Behandlung fehlerhafter Produkte bzw. die Vorgehensweise bei Betriebszuständen, die nicht dem Sollzustand entsprechen, ist in dokumentierten Standards festgelegt.
Hier ist die Beseitigung der Fehlerursachen und -auswirkungen beschrieben.
Für die Aufdeckung und Meldung von Schwachstellen, Abweichungen oder Fehlern sind alle Mitarbeiter zuständig. Die Koordination von Fehler-Ursachenanalysen, die Einleitung von Korrekturmaßnahmen sowie deren Überwachung liegen in der Verantwortung der Führungskräfte in den Organisationseinheiten.
Probleme in Form von Schwachstellen, Abweichungen und Fehlern können auftreten:

- an Produkten (einschließlich Produktdokumentation)
- in Fertigungsprozessen (einschließlich Prozeßbeschreibungen)
- im Qualitätsmanagementsystem (einschließlich Unterlagen)
- in der Mitarbeiterqualifikation
- in der Mitarbeitermotivation.

Externe Qualitätsinformationen bilden eine wesentliche Datenquelle für die Verbesserung der Qualität unserer Produkte und Dienstleistungen.
Hierbei unterscheiden wir zwischen:

- Reklamationen,
- Kundenäußerungen
- Briefe, Telefonate usw.

8.5.2 Corrective Action

The treatment of nonconforming products and the procedure to be followed in the case of operating processes which do not conform to their specified condition are defined in a documented standard.
This standard describes the elimination of the cause and effects of nonconformities.
All staff are responsible for uncovering and reporting weaknesses, deviations and nonconformities. Managers in the business units are responsible for coordinating analyses of nonconformities and their causes, and for introducing and monitoring corrective actions.
Problems can occur in the form of weaknesses, deviations and nonconformities, affecting:

- products (including product documentation)
- production processes (including process descriptions)
- quality management system (including documentation)
- staff skill
- staff motivation.

External quality information represents an important source of data for improving the quality of our products and services.
In this context we distinguish between:

- complaints,
- customer statements
- letters, phone calls etc.

Um die im DrägerService und Vertrieb anfallenden Informationen bewerten und analysieren zu können, ist ein System installiert, das auf folgenden Aktivitäten beruht:

- Bewertung jeder eingehenden externen Qualitätsinformation,
- Zusammenführung in einer Datenbank,
- Einleitung und Verfolgung von Korrektur- und Qualitätsverbesserungsmaßnahmen.

Die Ergebnisse der ergriffenen Maßnahmen werden aufgezeichnet.

Bei Vorfällen, die ihre Ursache in einem Produktfehler oder einer fehlerhaften Dienstleistung haben könnten und die dringende Korrekturmaßnahmen zur Abwendung von Gefahren erfordern, werden unmittelbar die namentlich benannten Ansprechpartner im Bereich Qualität, Umwelt, Standards informiert. Der weitere Ablauf wird vom Ansprechpartner im Bereich Qualität, Umwelt, Standards koordiniert und dokumentiert.

Es sind Korrekturmaßnahmen zur Beseitigung der aufgetretenen Abweichungen von den betrieblichen Vorgaben (z.B. Umweltziele, Normen, Meßgrößen) durchzuführen. Weiterhin sind die Ursachen dieser Abweichungen dauerhaft zu beseitigen.

A system has been installed to review and analyse the information generated at DrägerService and in the sales department. This system is based on the following activities:

- Evaluation of all incoming external quality information
- Collation of all information in a database
- Introduction and monitoring of corrective action and quality improvement measures.

The results of the action taken are recorded.

In the case of incidents which could be caused by a product nonconformity or a nonconforming service and which require urgent corrective action to avoid risks, the named contact persons at Quality, Environment, Standards are informed immediately. Further procedure is coordinated and documented by the competent point of contact at Quality, Environment, Standards.

Corrective action is to be taken to eliminate nonconformity to company requirements (e.g. environmental objectives, standards, measured variables). Furthermore, the causes of the nonconformity must be eliminated.

Dies ist ebenso gültig bei erkannten Abweichungen von festgelegten gesetzlichen und betrieblichen Vorgaben zum Umweltschutz und Arbeitssicherheit. Standards für die Einleitung von Korrektur- und Vorsorgemaßnahmen bei Eintritt einer Abweichung werden aufrechterhalten.

This applies equally to any noted nonconformity to the specified statutory and internal company environmental protection and occupational health and safety regulations.
Standards are maintained governing the introduction of corrective and preventive action in the event of nonconformity.

Wir haben Festlegungen getroffen, die die Regelung bei Unfällen oder Störungsfällen zum Inhalt haben. Hierzu werden Listen der Bereiche geführt (z.B. Lager und Anlagen) mit wesentlicher Gefährdung im Falle von Betriebsstörungen. Am Standort Lübeck ist ein EDV gestütztes Alarmierungssystem installiert worden, indem die wesentlichen Informationen hinterlegt wurden, um im Störungsfall schnell und effizient eingreifen zu können.

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We have defined regulations to deal with accidents and operational breakdowns. Lists of those departments (e.g. warehouses, plants and facilities) which are at particular risk from operational breakdowns are maintained. At the Lübeck plant a computer-assisted alarm system has been installed which provides essential information to allow quick and efficient action to be taken in the event of a breakdown.

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8.5.3 Vorbeugungs-maßnahmen

Die Vorgehensweise, wie mit angemessenen Vorbeugungsmaßnahmen das Auftreten potentieller Fehler verhindert wird, ist in einem dokumentierten Standard festgelegt. Potentielle Fehler und ihre Ursachen werden zum frühestmöglichen Zeitpunkt systematisch ermittelt, geeignete und angemessene Maßnahmen um das Auftreten von Fehlern zu verhindern ermittelt und umgesetzt. Die Ergebnisse der Maßnahmen werden aufgezeichnet und bewertet.

Vorbeugende Maßnahmen werden in der Designphase mittels der Fehler- Möglichkeits- und Einfluß Analyse durchgeführt. Zusätzlich sind die Nachweise für die Lastenhefterfüllung in Form von Qualifikationstests durchzuführen.

Korrektur- und Vorbeugungsmaßnahmen im Umweltschutz
Der bestellte Beauftragte und/oder der Bereich "Corporate Auditing" der Drägerwerk AG werden vom Prozeßverantwortlichen über die Abweichung und die eingeleiteten Maßnahmen informiert. Es wird geprüft, ob eine Meldung an die zuständige nationale Behörde erfolgen und die Öffentlichkeit informiert werden muß. Für Bereiche, die durch Tätigkeiten oder Prozesse ein besonderes Gefahrenpotential für die Umwelt darstellen, werden Notfall-, Alarm- und Meldepläne zur Vorbeugung und Abwendung der Gefahr erstellt.

8.5.3 Preventive Action

The procedure governing how appropriate preventive action is to be taken to prevent the occurrence of potential nonconformities is defined in a documented standard. Potential nonconformities and their causes are systematically determined at the earliest possible moment, and suitable and appropriate action is determined and implemented to prevent the occurrence of nonconformities. The results of action taken are recorded and evaluated.
Preventive action at the design stage is taken on the basis of the failure mode and effects analysis (FMEA). In addition, evidence of compliance with the customer requirements specification must be provided in the form of qualification tests.

Corrective and Preventive Action for Environmental Protection
The appointed environmental officer and/or Corporate Auditing at Drägerwerk AG are informed by the process owners about the nonconformity and the action initiated. It is checked whether the competent national authority and the public have to be informed. In areas whose activities or processes pose a particular potential risk to the environment, emergency, alarm and reporting plans are drawn up to prevent and eliminate such risks

Korrektur- und Vorbeugungsmaßnahmen für Arbeitssicherheit

Der Arbeitgeber, vertreten durch die Geschäftsleitung, ist durch nationale Gesetze verpflichtet, die Sicherheit und den Gesundheitsschutz seiner Arbeitnehmer am Arbeitsplatz zu gewährleisten. In seinem Auftrag kann die Wahrnehmung dieser Verpflichtung von bestellten Beauftragten durchgeführt werden. Die Arbeitnehmer und/oder bestellten Beauftragten haben Vortragsrecht gegenüber der Geschäftsleitung, die in begründeten Fällen die vorgeschlagenen Korrektur- und Vorbeugungsmaßnahmen genehmigen und die zur Durchführung notwendigen Mittel bereitstellen muß.

Corrective and Preventive Action for Occupational Health and Safety

The employer, represented by top management, is bound by national laws to ensure the safety and health of his employees at the workplace. At the employer's instruction, this duty can be made the responsibility of appointed officers. The employees and/or appointed officers have the right to recitation towards top management, who in justified cases must approve the proposed corrective and preventive action and provide the resources necessary to carry out this action.

Arbeitnehmer oder Risikogruppen, die aufgrund ihrer Tätigkeit besonderen Einwirkungen ausgesetzt sind, werden geschützt und einer präventivmedizinischen Überwachung unterzogen. Für Notfälle sind Maßnahmen zur Ersten Hilfe, Brandbekämpfung und Evakuierung der Arbeitnehmer erstellt, bekanntgeben und deren Wirksamkeit wird sichergestellt.

Employees or risk groups whose activities subject them to particular exposure are protected and subjected to a preventive medical examination. To deal with emergencies, first aid, fire control and personnel evacuation plans are drawn up, publicized and their effectiveness verified.

Den bestellten Beauftragten obliegt die Verpflichtung zur Überwachung eingeleiteter Maßnahmen, die Beurteilung der Wirksamkeit und deren Dokumentation.

The appointed officers have a duty to monitor, assess the effectiveness of and document the action initiated.

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9 Mitgeltende Standards / Additional Applicable Standards

Die nachfolgende Tabelle listet die wichtigsten mitgeltenden Standards zu den im Handbuch dargestellten Punkten auf.
The following table shows the main additional applicable standards at Dräger Safety with reference to the mentioned sections in the Quality Manual.

Section	Title	Additional Applicable Standard
4.2	Documentation Requirements Control of Documents	DSTN 0300 Principles to prepare standards and work instructions for the Safety Division DSTN 0311 Control of drawings, bills of material and manufacturing and inspection specifications DSTN 0320 Establishing of manuals and assign to the product DSTN 0332 Responsibilities for passing on Dräger manufacturing documents to contractors DSTN 0345 Grundsätze zum Datenaufwuchs EDB DSTN 0406 Manufacturing and inspection, preparation and change DSTN 0600 Control of external regulations DSTN 5913 Quality audit DWN 0309* Principles for control of documents DHGN 0500 Environmental Manual
	Control of Records	DSTN 0238 Feedback reporting system DSTN 0337 Handling of nonconforming products

Section	Title	Additional Applicable Standard
		DSTN 0426 Registration and operation of environmentally relevant systems and facilities DSTN 5053 First-articles inspection DSTN 5076 Special corrective actions DSTN 5913 Quality audits DSTN 5922 Design review and release DSTN 5923 Product test DSTN 5924 Reliability and safety studies DSTN 5935 Inspection planning DSTN 5951 Quality instructions and quality training DSTN 5965 Contract review DSTN 5966 Outside products, procedure for release and product placement PMR e000 Successful Project Management
5	Management Responsibility	0002e Quality reporting DSTN 0338 Benefit from Claims
6	Resource Management	DSTN 5951 Quality instructions and quality training DSTN 0426 Registration and operation of environmentally relevant systems and facilities

Section	Title	Additional Applicable Standard
		DWN 333 Clean room technology DHGN 0434 Environmentally compatible energy- and water management DHGN 0443 Determination of environmental goals and definition of environmental programmes
7.1	Planning of Product Realization	PMR e000 Sucessful Project Management DSTN 5922 Design review and release DHGN 0435 Environmentally compatible design of devices
7.2	Customer Related Processes	DSTN 5965 Contract review DSTN 0238* Feedback reporting system DSTN 5924 Reliability and safety studies DSTN 5079 Quality assurance for customer - specific projects and in systems engineering and construction
7.3	Design and Development	PMR e000 Sucessful Project Management DSTN 5922 Designreview and release DHGN 0435 Environmentally compatible design of devices DSTN 5921 Product quality definition DWN 0417 Component age control DWN 5961 Service quality planning

Section	Title	Additional Applicable Standard
		DSTN 5974 Classification of characteristics and processes DSTN 5924 Reliability and safety studies DSTN 5925 Definition of product quality, development assessment and release for software DSTN 5931 Process quality definition DSTN 5966 Outside products, procedure for release and product placement
7.4	Purchasing	DSTN 5053 First- article inspection DSTN 5935 Inspection planning DSTN 5941 Quality assurance in external procurement DWN 310 Esquire about purchased material DSTN 5934 Quality inspection in production, procurement and at maintenance DWN 412 Introduction of harmful substances DWN 413 Handling of harmful substances
7.5	Production and Service Provision	DSTN 5931 Process quality definition DSTN 5932 Process capability studies DSTN 5934 Quality inspection in production, procurement and at maintenance DSTN 5033 Application of sampling plans

Section	Title	Additional Applicable Standard
		DSTN 5924 Reliability and safety studies DSTN 0426 Registration and operation of environmentally relevant systems and facilities DHGN 0500 Environmental Manual DWN 413 Handling of harmful substances DHGN 0321 Sales- and dispatch packaging DHGN 0322 Packaging of supply goods DWN 324 In- house packings DWN 333 Clean room technology DWN 398 Packaging and storage of parts and semi-finished products in the clean room DWN 449 Ageing control of auxiliary materials with shelf-life DWN 3013 Handling of electrostatic endangered parts and units DSTN 0336 Blocking and unblocking in sales storage DSTN 0337 Handling of nonconforming products DSTN 0319 Manufacturing and / or delivery stop DSTN 0418 Devices and components with obligatory registration

Section	Title	Additional Applicable Standard
		DWN 401 Schedule of part numbers DWN 419 Serial numbers DWN 0417 Component age control DSTN 5054 Inspection of material for German Bundeswehr in accordance with maintenance contracts DSTN 5066 Test documents for quality inspections during maintenance of Dräger products DSTN 5934 Quality inspection in production, procurement and at maintenance DWN 5961 Service quality planning DHGN 0501 Manual of dangerous goods DHGN 0424 Disposal of waste materials
7.6	*Control of Monitoring and measuring Devices*	DSTN 5086 Surveillance of control, measuring and test equipment, handling maintenance and measuring value deviations DSTN 5087 Surveillance of control, measuring and test equipment, calibration DSTN 5972 Test equipment specifications
8.2.1	Customer Satisfaction	DSTN 0238* Feedback reporting system DSTN 5962 External quality information

Section	Title	Additional Applicable Standard
		0002e Quality reporting
8.2.2	Internal Audit	DSTN 5913 Quality audit
8.2.3	Monitoring and Measurement of Processes	DSTN 5923 Product test DSTN 5924 Reliability and safety studies DSTN 5932 Process capability studies 0002e Quality reporting
8.2.4	Monitoring and Measurement of Product	DSTN 5935 Inspection planning DSTN 5012 Quality stamps DSTN 5053 First - article inspection DSTN 5934 Quality inspection in production, procurement and at maintenance DSTN 5033 Application of sampling plans DSTN 5925 Definition of product quality, development assessment and release for software DSTN 5923 Product test
8.3	Control of Nonconforming Products	DSTN 0319 Manufacturing and / or delivery stop DSTN 0336 Blocking and unblocking in sales storage DSTN 0337 Handling of nonconforming products

Section	Title	Additional Applicable Standard
		DSTN 0238* Feedback reporting system
8.4.	Analysis of Data	0002e Quality reporting
8.5.1 8.5.2 8.5.3	Continual improvement Corrective Action Preventive Action	DSTN 0238* Feedback reporting system DSTN 0319 Manufacturing and / or delivery stop DSTN 0338 Using complaint, flowchart in the business unit DSTN 5076 Special corrective actions DSTN 5962 External quality informations DHGN 0432 Environmental interference management DSTN 0426 Registration and operation of environmentally relevant systems and facilities DHGN 0500 Environmental Manual DHGN 0439 Handling of environmentally relevant interferences

*International Standard
Documented procedure required

7

ATTACH G

Draeger Safety Inc.
Quality System Manual

Instructions For Use

When browsing through this document you will find hyperlinks that make navigating faster and more convenient. When you double click a hyperlink, you are directly taken to a reference part of the document that explains the subject in greater detail. Also there are hyperlinks that return you to the table of contents. For example:

By double clicking the section Product Realization in the table of contents, you will be taken to that part of the document that explains product realization in more detail.

By double clicking the symbol 🕮, found in many of the sections, you will be returned to the top of the table of contents.

Note: A hyperlink is indicated by underlined blue text that makes the cursor turn into a hand. After a hyperlink has been used at least once its color turns to purple.

Effective Date: July 1, 2002

Approved: Wes Kenneweg
President

Approved: Steve Meyer
Management Representative

1.0 Table of Contents

2.0 Introduction

Draeger Safety Inc. believes that quality plays a vital and increasing role in all of our present and future business activities. Customers expect products and services to be provided according to their requirements and without omissions. To this end, Draeger Safety has chosen the ISO-9001: 2000 International Standard as the foundation of our Quality Management System.

2.1 Company Profile

Headquartered in Pittsburgh, Pennsylvania, Draeger Safety is the United States subsidiary of Draeger Safety AG & Co. KGaA , located in Lübeck, Germany. Draeger's worldwide manufacturing, sales and service organizations are comprised of more than 20 subsidiaries and holding companies, generating annual revenues over one billion dollars. Draeger Safety has provided high tech, quality safety products to American industries for over 20 years. Draeger Safety is located in a 60,000 square foot development and manufacturing facility and has over 180 employees experienced and committed to providing high quality gas detection and respiratory protection equipment in the industry.

References

- ISO 9001:2000(E), Quality management systems - Requirements - Model for quality assurance in design, development, production, installation and serving.
- ISO 9004:2000 (E), Quality management systems - Guidelines for performance improvements
- ISO 9000:2000(E), Quality management systems - Fundamentals and vocabulary

3.0 Quality Philosophy

3.1 Declaration of Commitment by Management

Draeger Safety Inc. management has approved and implemented the quality management system described in this Quality Manual.

All employees are required to comply with the requirements, standards and instructions as prescribed by this Quality System Manual. Compliance is an essential prerequisite for retaining certification of the company's quality management system in accordance with ISO 9001. All company managers have a duty to ensure that their employees are familiar with, understand and observe those parts of the Quality Manual, standards and instructions that are of relevance to their work.

Vision, Mission, Values, Quality Policy, Breakthrough & Organizational Goals & Objectives

See appendix "A"

Organizational Chart Draeger Safety Inc.

See appendix "B"

Process Management

See appendix "C"

3.2 Our Quality Management Principles

The principles set out below form the basis for our activities. In the company-wide Business Excellence training courses, our employees have been taught the methods they need to apply these principles. Ongoing Business Excellence assessments and reviews measure and verify that the principles are effective.

See Appendix "D"

3.3 Quality System Audits

The system is regularly audited by the following external bodies:

Underwriters Laboratories Inc., Northbrook, Illinois

NIOSH (National Institute for Occupational Safety and Health, USA)

4.0 Quality Management System

The quality management system at Draeger Safety is documented in this manual and in various other process descriptions and standards in accordance with ISO 9001: 2000.

4.1 General Requirements

4.1.1 General Requirements

DSI (Draeger Safety Inc.) identifies business processes, determines the sequence and interaction of those processes, and determines the criteria & methods for operation & control of those processes. DSI ensures the availability of resources & information to support the operation & monitoring of its Processes. DSI monitors, measures & analyzes its processes and implements actions to achieve processes improvement.

References

Activity	Procedure
a) Identify Processes	Appendix C
b) Determine sequence and interaction of processes	Appendix C and Process Mapping Folder
c) Determine criteria & methods for operation & control of Processes	DSN 5904
d) Ensure availability of resources & information to support operation & monitoring of Processes	DSN 5902
e) Monitor, measure & analyze processes	DSN 5904 and Process Mapping Folder
f) Implement actions to achieve results and improvement of processes	DSN 5902

4.2 Documentation Requirements

4.2.1 General

DSI's Quality Policy, Quality Objectives, and Quality System Policy Manual is documented. Procedures and records that are required by the ISO 9001: 2000 Standard are also documented and maintained including procedures for planning, operating, and control of its processes. The Quality System is reviewed, supported and put into force by top management.

References

Activity	Procedure
a) Documented Quality Policy and Quality Objectives	Appendix A
b) Documented Quality Manual	This Quality System Manual
c) Document procedures called for in the standard	Referenced within Quality System Manual
d) Documented procedures for planning, operation & control of processes	Referenced within Quality System Manual
e) Records required by the standard	DSN 5991 and Quality Records Matrix

4.2.2 Quality Manual

This Quality Manual describes Draeger Safety Inc's quality management system and is applicable for Draeger Safety Inc. located in Pittsburgh, Pa. and its sales and service offices. All Quality System Procedures are referenced or listed according to application. Interactions between processes are described in process flow diagrams.

References

Activity	Procedure
a) Define the scope of QMS	Within Quality System Manual
b) Define the documented procedures established or reference to them	Referenced within Quality System Manual
c) Describes the interaction between processes	Process Mapping Folder

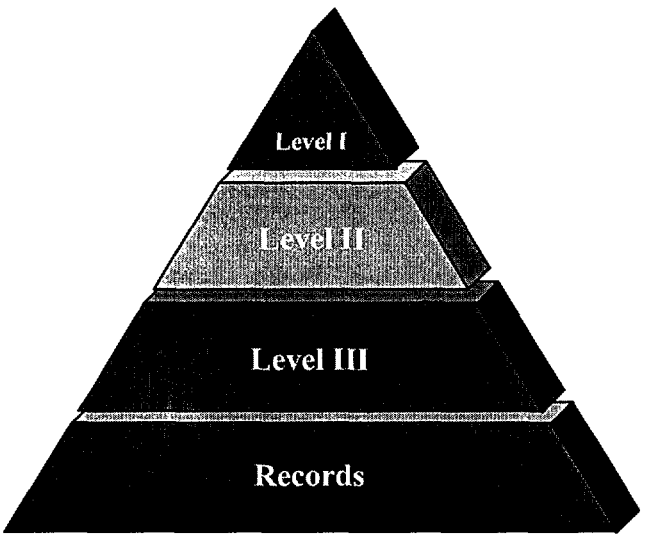
4.2.3 Control Of Documents

Documents are controlled in accordance with a documented procedure. The following matrices indicates the activity and the procedure that controls that activity:

References

Activity	Procedure
a) Documented procedure to approve documents	DSN 5100, DSN 5102, DSN 5913
b) Documented procedure to review & update and re-approve documents	DSN 5100, DSN 5102, DSN 5913
c) Documented procedure to ensure changes & current revision of documents are identified	DSN 5100, DSN 5102, DSN 5913
d) Documented procedure to ensure relevant versions are available at points of use	DSN 5100, DSN 5102, DSN 5913
e) Documented procedure to ensure documents remain legible and identifiable	DSN 5100, DSN 5102, DSN 5913
f) Documented procedure to identify and control external documents	650WI-01
g) Documented procedure to prevent unintended use of obsolete documents and their identification	DSN 5100, DSN 5102, DSN 5913

The quality system documentation and records is structured as follows:



Level I Procedures: Draeger Safety, Inc. Quality System Manual (DSN 5900)

Level II Procedures: Draeger Safety, Inc. Normative (DSN)

Level III Procedures: Draeger Safety, Inc. Work Instructions

Records: Draeger Safety, Inc. Quality System Records

4.2.4 Control of Records

Records are established and maintained to provide evidence of conformance to the Quality System. Records are controlled to maintain legibility and are identifiable and retrievable. Documented procedures are maintained to provide controls for identification, storage, protection, retrieval, retention time and disposition.

References

Activity	Procedure
1. Records to provide evidence of conformance are established and maintained.	DSN 5991 and Quality Records Matrix
2. Records are to remain legible, identifiable and retrievable.	DSN 5991 and Quality Records Matrix
3. Documented procedure to define the controls for identification, storage, protection, retrieval, retention time and disposition are defined	DSN 5991 and Quality Records Matrix

5.0 Management Responsibility 🕮

5.1 Management Commitment

DSI communicates the importance and relevance of customer, statutory and regulatory requirement to the appropriate persons. The Quality Policy and Quality Objectives are communicated, posted, and understood at all levels of the organization. Management Review meetings are conducted to discuss the application and implementation of this information. Resource allocation and availability is managed at the senior management level.

References

Activity	Procedure
a) Communicate the importance of customer, statutory and regulatory requirements	Accomplished during Quarterly Employee Meetings Bulletin Board Postings
b) Document the Quality Policy	Appendix A
c) Document the Quality Objectives	Appendix A
d) Conduct Management Reviews	DSN 5902
e) Availability of resources	DSN 5902

5.2 Customer Focus

Customer requirements are determined through contract reviews, marketing, surveys, and other means. In order to meet customer requirements, they are translated into customer specifications and finalized in the product realization process. Feedback from customers is measured and processed to improve and enhance customer satisfaction.

References

Activity	Procedure
1. Determine customer requirements	DSN 5951 and DSIN 7.3.01
2. Meet customer requirements	DSN 5951 and DSIN 7.3.01
3. Enhance customer satisfaction	DSN 5115, DSN 5918 and DSN 5952

5.3 Quality Policy

The Quality Policy Statement indicates DSI's intent to provide quality products and services to our customers (See Appendix A). The Quality System Policy Manual includes DSI's commitment to comply with QMS requirements and to continually improve the effectiveness of the QMS. QMS performance is reviewed at least semi-annually for appropriateness and suitability. Quality System Policy is the framework for developing and reviewing the Quality Objectives and is communicated and understood within the organization.

References

Activity	Procedure
a) Policy is appropriate	DSN 5902
b) Policy states commitment to comply with requirements and continuous improvement of the QMS	Within this Quality System Manual
c) Policy provides framework for reviewing quality objectives	Within this Quality System Manual
d) Policy is communicated and understood within the organization	Accomplished during Quarterly Employee Meetings Bulletin Board Postings
e) Policy is reviewed for suitability	DSN 5902

5.4 Quality Management System Planning

Quality Objectives are established for the product, process, and service activities. Quality Objectives are tracked and measured and are consistent with the Quality Policy. Planning of the Quality Management System is in accordance with the following:

a) Processes identification
b) Process sequence and interaction
c) Process criteria & methods for operation & control
d) Availability of resources & information to support operation & monitoring of processes
e) Process monitoring, measurement & analyzing
f) Process continual improvement

Process and Departmental Managers are responsible for implementing the quality management system and to maintain the integrity of the Quality Management System when changes are implemented.

References

Activity	Procedure
1. Quality Objectives are established, including those for product	Appendix A
2. Quality Objectives are measured and are consistent with Quality Policy.	Appendix A
Quality Management System Planning	Appendix G and Appendix H
a) Planning of the QMS is carried out to meet requirements of paragraph 4.1 and the quality objectives	Appendix G and Appendix H
b) Integrity of the quality management system is maintained when changes are planned & implemented	Appendix G and Appendix H

5.5 Responsibility, Authority & Communication

Responsibilities and Authorities

Responsibilities and authorities are defined in employees job descriptions and QMS procedures and work instructions.

References

Activity	Procedure
Responsibility & Authority	
1. Define responsibilities	Within Job Descriptions and procedures
2. Define authorities	Within Job Descriptions and procedures
3. Communicate responsibilities and authority within the organization	Within Procedures and Organizational Chart (Appendix B)

Management Representative

The Quality Manager holds the position of management representative. The Management Representative has responsibility and authority to ensure that processes are established, implemented and maintained. The Management Representative has responsibility and authority to report on performance of the quality management system and need for improvement. The Management Representative has responsibility and authority to promote awareness of customer requirements throughout the organization.

In addition he is appointed directly by top management, lays down the guidelines for quality management and updates the goals for implementation of the quality management system in the organization. The management representative acts as the liaison for customers and suppliers, institutions and authorities in all questions relating to the quality management system.

The duties of Quality Standards can be summarized as follows:

Establish and update Organizational Performance Objectives
Conduct internal quality
Compile quality reports to illustrate and evaluate QMS effectiveness
Managing and distributing high-level process procedures

Internal Communication

A communication process is established that communicates customer requirements, customer satisfaction, quality goals & performance, and QMS requirements.

References

Activity	Procedure
Management Representative	
a. Management Representative has responsibility and authority to ensure processes are established, implemented and maintained	DSN 5902 and Job Description
b) Management Representative has responsibility and authority to report on performance of the quality management system and need for improvement	DSN 5902 and Job Description
c) Management Representative has responsibility and authority to promote awareness of customer requirements throughout the organization	DSN 5902 and Job Description
1. Establish communication processes	Quarterly Employee Meeting
2. Communicates the effectiveness of the QMS	DSN 5902

5.6 Management Review

General

Top management reviews the suitability, adequacy, and effectiveness of the QMS twice annually. The results of those reviews and other operational information such as internal audits, are the basis for improvement and changes to the system, Quality Policy, and Quality objectives. Records are maintained of all Management Reviews.

References

Activity	Procedure
1. Top Management shall review the QMS at planned intervals	DSN 5902
2. Top Management ensures suitability, adequacy and effectiveness	DSN 5902
3. Top Management assesses opportunities for improvement and need for changes to include Quality Policy and Quality Objectives	DSN 5902
4. Records are maintained	DSN 5991 and Quality Records Matrix

Review Input

The following items are review at the Management Review meeting:

a) Results of audits
b) Customer feedback
c) Process performance and product conformity
d) Status of preventive and corrective actions
e) Follow-up actions from previous management reviews
f) Changes that could affect the QMS
g) Recommendations for improvement

Activity	Procedure
a) Results of audits	DSN 5902
b) Customer feedback	DSN 5902
c) Process performance and product conformity	DSN 5902
d) Status of preventive and corrective actions	DSN 5902
e) Follow-up actions from previous management reviews	DSN 5902
f) Changes that could affect the QMS	DSN 5902
g) Recommendations for improvement	DSN 5902

Review Output

The following actions result from the Management Review meeting:

a) Actions to improve the effectiveness of the QMS or its processes
b) Actions to improve the product as it relates to customer requirements
c) Actions to address resource needs

References

Activity	Procedure
a) Actions to improve the effectiveness of the QMS or its processes	DSN 5902
b) Actions to improve product related to customer requirements	DSN 5902
c) Actions to address resource needs	DSN 5902

6.0 Resource Management 🕮

6.1 Provision Of Resources

Resources are provided to implement and maintain the QMS and improve its effectiveness. The results of these efforts enhance customer satisfaction by meeting customer requirements.

Activity	Procedure
Provision Of Resources	
a) Resources to implement and maintain QMS and improve its effectiveness	Resource Allocation Team (Human Resources)
b) Resources to enhance customer satisfaction by meeting customer requirements	Resource Allocation Team (Human Resources)

6.2 Human Resources

General

Employees are prepared and competent on the basis of education, skills, and training.

Activity	Procedure
1. Personnel shall be competent on basis of education, training, skills and experience	DSN 5971 and Job Descriptions

Competence & Awareness Training

DSI performs Competence & Awareness Training by:

a) Determining the necessary competence level of personnel
b) Providing training or other actions to satisfy determined training needs
c) Evaluating the effectiveness of competence, and training
d) Ensuring that personnel are aware of their relevance and importance to meeting Quality Objectives
e) Maintaining appropriate records of education, training, skills and experience

References

Activity	Procedure
a) Organization shall determine necessary competence of personnel	Job Descriptions and DSN 5971 with reference to Department Training Guidelines
b) Organization shall provide training or other actions to satisfy training needs	DSN 5971 with reference to Department Training Guidelines
c) Organization shall evaluate effectiveness of actions taken to address competence, awareness and training	DSN 5971 with reference to Department Training Guidelines
d) Organization shall ensure personnel are aware of their relevance and importance to meeting Quality Objectives	Accomplished during Quarterly Employee Meetings Bulletin Board Postings
e) Organization shall maintain appropriate records of education, training, skills and experience	DSN 5971

6.3 Infrastructure

DSI determines the need for, provision, and maintenance of buildings, workspace, and associated utilities. DSI also determines the need for, provision, and maintenance of process equipment including hardware, software and supporting services.

References

Activity	Procedure
a) Determine, provide and maintain buildings, workspace and associated utilities	Budget Meeting (Graeme Roberts / Walter Schaller)
b) Determine, provide and maintain process equipment to include hardware and software	DSIN 7.3.01 and DSN 5932
c) Determine, provide and maintain supporting services	Budget Meeting (Graeme Roberts / Walter Schaller)

6.4 Work Environment

DSI determines and manages the work environment to achieve conformity to product requirements.

References

Activity	Procedure
1. Determine and manage work environment to achieve conformity to product requirements	DSIN 7.3.01 and DSN 5932

7.0 Product Realization

7.1 Planning For Product Realization

The realization of a new product is a documented and planned process. This process includes determining quality objectives and requirements of the product. The process also includes provisions for determining the requirement for realization processes, documents, and resources specific to the product. The required verification, validation, monitoring, inspection and test activities specific to the product and the acceptance criteria are identified. Records are identified and maintained to provide evidence that the processes and resulting product meet requirements. Planning takes place in three phases:

Ideas phase

Definition phase

Realization phase

The planning phase takes into account at the least the following elements: product objectives, product strategy, customer requirements, economic efficiency, risks, production and service concept. The result of the idea phase is a decision whether to proceed to the definition phase. In this case, a project order is documented. The definition phase includes a more detailed plan of the project and ends with a project review that forms the decision-making basis for proceeding to the realization phase. The quality objectives and requirements for the product and as necessary, verification, validation, monitoring, inspection and test activities, are documented in the customer requirements specification and technical requirements specification. Customer requirements, relevant standards, and legal requirements considered during this phase (in particular requirements from EC & US Directives such as "Personal Protective Equipment" and "Explosion Prevention"). In the realization phase, project and market data are used for the implementation of the plan. Progress is monitored in specified project reviews. The course of the entire project is recorded in a project file. The appointed project manager is responsible for achieving the project objectives with the planned resources, within the intended time scale, and without exceeding the budgeted costs. The project team and/or participating specialist departments are responsible for specified tasks.

References

Activity	Procedure
a) Determine quality objectives and requirements of the product	DSIN 7.3.01
b) Determine the need for processes, documents and provide resources specific to the product	DSIN 7.3.01
c) Determine the required verification, validation, monitoring, inspection and test activities specific to the product and the acceptance criteria	DSIN 7.3.01
d) Determine the records needed to provide evidence that the processes and resulting product meet requirements Note 1 Document the Quality Plan for Product	DSIN 7.3.01

7.2 Customer Related Processes

7.2.1 Determination of Requirement Related to the Product

For the product to be realized, requirements from customers (including delivery activities) and requirements necessary for intended use, statutory laws and regulations, and other organizational requirements are considered.

References

Activity	Procedure
a) Determine requirements specified by the customer to include delivery and post-delivery activities	DSIN 7.3.01 and DSN 5951
b) Determine requirements not stated by the customer but necessary for specified or intended use	DSIN 7.3.01 and DSN 5951
c) Determine statutory and regulatory requirements related to the product	DSIN 7.3.01 and DSN 5951
d) Determine any additional requirements	DSIN 7.3.01 and DSN 5951

7.2.2 Review of Requirement Related to the Product

The planning process includes reviews to ensure that product requirements are defined, contract order requirements differing from previous ones are resolved, and DSI has the ability to meet defined requirements. Records of reviews are maintained. In cases when documented statement of requirements are not given, requirements are confirmed before contract acceptance. When product requirements change, DSI ensures that relevant documents are revised and personnel are aware of the changes.

References

Activity	Procedure
a) Ensure product requirements are defined	DSN 5951
b) Ensure contract or order requirements differing from previous ones are resolved	DSN 5951
c) Ensure organization has ability to meet defined requirements	DSN 5951
1. Records of review are maintained	DSN 5951
2. When no documented statement of requirements is given, requirements are confirmed before acceptance	DSN 5951
3. When product requirements are changed, the organization must ensure relevant documents are revised and personnel are aware of changed requirements	DSN 5951

7.2.3 Customer Communication

DSI is in constant communication with customers to pass on relevant product information, customer inquiries, contracts, and order handling to include changes or amendments and feedback on customer complaints.

Active communication with customers takes place via personal contact between customers and the sales and service organization. It also takes place through the company's own customer journal (Draeger Review), the internet, and publication of specific telephone numbers and email addresses in product information brochures. Prior to publication, all product information undergoes an inspection and release process.

References

Activity	Procedure
a) Communicate to the customer on product information	Product Information Bulletins 040 WI 01
b) Communicate to the customer on inquiries, contracts or order handling to include amendments	DSN 5951
c) Communicate to the customer on customer feedback to include customer complaints	DSN 5115, DSN 5918 and DSN 5952

7.3 Design & Development

The design and development of new products and the modification of existing products is a planned and controlled process. It consists of a number of defined phases as indicated.

See Appendix "E"

The appointed project manager is responsible for achieving the project objectives with the planned resources within the intended time scale. The Project Manager is responsible for planning, coordinating and supervising the entire design and development project and for maintaining and updating the project documentation. The project team and/or participating specialist departments are responsible for individual tasks.

Each design phase ends with a project review. The actual project status achieved is reviewed and documented on the basis of review lists specifically designed for this purpose. When necessary, plans are updated. Release approval of the individual design phases by appointed managers ensures that the actual design and development status is consistent with the design input requirements. If the review of the outputs is positive, the next stage of the project is released.

Documentation is provided in the form of the project file, ensuring the traceability of all design phases. In the event of deviations, the project manager defines actions to ensure that the specified objectives are achieved.

In the design phase, laboratory tests, tests with field trial units, and production prototypes are planned and conducted. Product tests verify the product's functionality, performance, reliability and safety at each stage of the project. The test results are evaluated and are compared to the requirements from the customer requirement specification. The results and necessary actions are recorded.

Design and development outputs must provide the necessary information and requirements for purchasing, production and for service provision and specify product acceptance criteria and the characteristics of the product that are essential for its safe and proper use.

7.3.1 Design & Development Planning

The design and development phases are determined according to procedure. Product and process review phases occur according to plan to verify and validate each stage of the design. Assigned responsibilities and authorities for design and development are made prior to beginning the project including the management of interfaces between groups for effective communications and assignment of responsibilities. Planning output is updated as the design and development activities progress.

References

Activity	Procedure
a) Determine the design and development stages	DSIN 7.3.01
b) Determine the appropriate review, verification and validation for each stage of the design	DSIN 7.3.01
c) Determine responsibilities and authorities for design and development	DSIN 7.3.01
Manage interfaces between groups to ensure effective communications and assignment of responsibilities	DSIN 7.3.01
Planning output shall be updated as appropriate as design and development progresses	DSIN 7.3.01

7.3.2 Design & Development Inputs

Design & development input records are identified and determine for product function & performance, regulatory requirements, information derived from previous similar designs, and for other relevant requirements for design and development. Inputs are reviewed for adequacy, completeness, ambiguity, and the elimination of conflict with each other.

References

Activity	Procedure
a) Determine and maintain records for functional and performance	DSIN 7.3.01, DSN 5991 and Quality Records Matrix
b) Determine and maintain records for statutory and regulatory requirements	DSIN 7.3.01, DSN 5991 and Quality Records Matrix
c) Determine and maintain records for information derived from previous similar designs	DSIN 7.3.01, DSN 5991 and Quality Records Matrix
d) Determine and maintain records for any other requirements for design and development	DSIN 7.3.01, DSN 5991 and Quality Records Matrix
1. Inputs are reviewed for adequacy and shall be complete and unambiguous and not in conflict with each other	DSIN 7.3.01

7.3.3 Design & Development Outputs

Design & development outputs are planned to meet input requirements, provide appropriate information for purchasing, production and service activities, and contain or reference product acceptance criteria. Outputs specify characteristics of the product that are essential for its safe and proper use.

References

Activity	Procedure
a) Outputs shall meet input requirements	DSIN 7.3.01
b) Outputs shall provide appropriate information for purchasing, production and service	DSIN 7.3.01
c) Outputs shall contain or reference product acceptance criteria	DSIN 7.3.01
d) Outputs shall specify characteristics of the product that are essential for its safe and proper use	DSIN 7.3.01 and DSN 5974

7.3.4 Design & Development Review

Design development reviews are conducted to evaluate the ability of the results so that they meet requirements. Reviews are conducted to identify problems and propose necessary actions Participants in reviews include representatives from functions concerned with design. Records of the results of the reviews and necessary actions are maintained.

Activity	Procedure
a) Reviews are conducted to evaluate the ability of the results to meet requirements	DSIN 7.3.01
b) Reviews are conducted to identify problems and propose necessary actions	DSIN 7.3.01
1. Participants in reviews shall include representatives from functions concerned with design	DSIN 7.3.01
2. Records of the results of the reviews and necessary actions shall be maintained	DSIN 7.3.01, DSN 5991 and Quality Records Matrix

7.3.5 Design & Development Verification

Design & development verification is in accordance with the Design Plan. Records of the verification activities and any necessary corrective actions are maintained.

References

Activity	Procedure
1. Verification shall be performance with Design Plan	DSIN 7.3.01
2. Records of the verification and any necessary action shall be maintained	DSIN 7.3.01, DSN 5991 and Quality Records Matrix

7.3.6 Design & Development Validation

Design & development Validation is performed to ensure that the resulting product meets requirements of specified application or intended use. Validation is completed prior to delivery of the product or service. Records of validation results and necessary actions are maintained.

References

Activity	Procedure
1. Validation shall be performed in accordance with Design Plan	DSIN 7.3.01
2. Validation shall ensure resulting product meets requirements of specified application or intended use	DSIN 7.3.01
4. Records of validation results and any necessary actions shall be maintained	DSIN 7.3.01, DSN 5991 and Quality Records Matrix

7.3.7 Control of Design & Development Changes

Design & Development Changes are identified and recorded. Changes are reviewed, verified and validated, and approved before implementation. Major design changes are treated as new developments. Design changes include an evaluation of the effects of the change on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained.

References

Activity	Procedure
1. Design changes are identified and recorded	DSIN 7.3.01 and DSN 5913
2. Changes are reviewed, verified and validated, and approved before implementation	DSIN 7.3.01 and DSN 5913
3. Design changes shall include evaluation of the effect of the changes on constituent parts and product already delivered	DSIN 7.3.01 and DSN 5913
4. Records of the results of the review of changes and any necessary actions shall be maintained	DSIN 7.3.01, DSN 5913, DSN 5991 and Quality Records Matrix

7.4 Purchasing

7.4.1 Purchasing Process

DSI ensures that purchased product meets requirements. The degree of control of suppliers is dependent on the purchased product. DSI selects and evaluates suppliers based on their ability to met specified requirements. The criteria for selecting, evaluating and re-evaluating suppliers are documented. Records are maintained from the evaluation and necessary actions arising from the evaluation of suppliers.

References

Activity	Procedure
1. Ensure purchased product meets requirements	DSN 5103, DSN 5933, 068 WI 05
2. Control of suppliers is dependent on purchased product provided	DSN 5941 and DSN 5943
3. Ensure selection and evaluation of suppliers is based on their ability to met requirements	DSN 5941 and DSN 5943
4. Establish criteria for selecting, evaluating and re-evaluating suppliers	DSN 5943
5. Maintain records of the evaluation and any necessary actions arising from evaluation of suppliers	DSN 5941, DSN 5991 and Quality Records Matrix

7.4.2 Purchasing Information

Purchasing information is described for the purchased product and the requirements for product approval, procedures, processes and equipment. Purchasing information also describes personnel requirements and quality management system requirements. DSI ensures the adequacy of specified requirements prior to communicating to the supplier.

Activity	Procedure
a) Purchasing information shall describe for the product to be purchased and requirements for approval of product, procedures, processes and equipment	DSN 5103, 068 WI 05 and 068 WI 01
b) Purchasing information shall describe the product to be purchased and requirements of personnel	DSN 5103, 068 WI 05 and 068 WI 01
c) Purchasing information shall describe the product to be purchased and quality management system requirements	DSN 5103, 068 WI 05 and 068 WI 01
1. Ensure adequacy of specified requirements prior to communication to the supplier	DSN 5103 and 068 WI 05

7.4.3 Verification of Purchased Product

DSI verifies, at location, by establishing and implementing inspection or other activities to ensure that the purchased product meets requirements. Purchasing documents contain information when verification at the supplier's location is required by the organization or customer.

References

Activity	Procedure
1. Verify at location by establishing and implementing inspection or other activities to ensure purchased product meets requirements	Within Quality Systems Manual
2. State in purchasing information when verification at the supplier's location is required by the organization or customer	Within Quality Systems Manual

7.5 Production & Service Provision

7.5.1 Control of Production & Service Provision

DSI ensures that production and service activities are carried out under controlled conditions. These controlled conditions ensure that information that describes characteristics of the product is available, necessary work instructions are available, suitable equipment is used during production & servicing activities, monitoring & measuring equipment is available & implemented during production & servicing activities, and that release, delivery and post-delivery activities are implemented as necessary.

References

Activity	Procedure
1. Production and service shall be carried out under controlled conditions	DSN 5932 and DSN 5981
a) Ensure the availability of information that describes characteristics of the product	DSN 5974 and DSN 5981
b) Ensure as necessary that work instructions are available	DSN 5913, DSN 5932, DSN 5981, and DSN 5100
c) Ensure suitable equipment is used during production and servicing	DSN 5932 and DSN 5981
d) Ensure the availability and use of monitoring and measuring equipment during production and servicing as necessary	DSN 5932, DSN 5961 and DSN 5981
e) Ensure the implementation of monitoring and measuring during production and servicing as necessary	DSN 5932, DSN 5961 and DSN 5981
f) Ensure the implementation of release, delivery and post-delivery activities as necessary	DSN 5933, DSN 5981and 068 WI 03

7.5.2 Validation of Production & Service Provision Processes

Processes are validated when a resulting output cannot be verified by monitoring or measurement or where deficiencies become apparent after the product is in use or in service. DSI ensures that criteria is defined for the review and approval of processes, equipment is approved and personnel are qualified, the use of specific methods and procedures, records are maintained for the processes, and necessary revalidation of processes.

References

Activity	Procedure
1. Validate processes where resulting output cannot be verified by monitoring or measurement to include processes where deficiencies become apparent after product is in use or service delivered	DSIN 7.3.01, DSN 5932 and DSN 5933
2. Validation shall demonstrate ability of processes to achieve planned results	DSIN 7.3.01, DSN 5932 and DSN 5933
a) Ensure criteria has been defined for the review and approval of processes	DSIN 7.3.01, DSN 5974, DSN 5932 and DSN 5933
b) Ensure equipment is approved and personnel are qualified	DSN 5932 and DSN 5971
c) Ensure use of specific methods and procedures	DSN 5932
d) Ensure records are maintained for the processes	DSN 5991 and Quality Records Matrix
e) Ensure the revalidation of processes	DSN 5932

7.5.3 Identification & Traceability

DSI ensures that product is identified by a suitable means throughout product realization, that the product has an identifiable status with respect to monitoring and measurement requirements, and that the unique identification of product is controlled and recorded.

References

Activity	Procedure
1. Identify product by suitable means throughout product realization	DSN 5931, DSN 5932 and DSN 5933
2. Identify product status with respect to monitoring and measurement requirements	DSIN 7.3.01, DSN 5932 and DSN 5933
3. Control and record the unique identification of product	DSN 5991 and Quality Records Matrix
NOTE: Configuration management can be used for identification and traceability	

7.5.4 Customer Property

In cases when a product is under the care and control of DSI, controls are applied to identify, verify, protect and safeguard the customer property. When the customer property is lost, damaged or unsuitable for use, DSI will report the situation to the customer. Records of customers lost property, damage or unsuitable for use will be maintained.

References

Activity	Procedure
1. Exercise care with customer product when under organization's control	DSN 5937
2. Identify, verify, protect and safeguard customer property	DSN 5937
3. Customer property lost, damaged or unsuitable for use shall be reported to the customer	DSN 5937
4. Records of customer property lost, damaged or unsuitable for use shall be maintained	DSN 5937, DSN 5991 and Quality Records Matrix

7.5.5 Preservation of Product

Controls to preserve conformity of the product during internal processing and intended destination delivery are implemented. Products and components are identified, handled, packaged and protected in such a manner as to prevent damage or nonconformity.

References

Activity	Procedure
1. Preserve conformity of product during internal processing and intended destination delivery	DSN 5936
2. Products and components shall be identified, handled, packaged and protected in such a manner as to prevent damage or nonconformity	DSN 5936 and 068 WI 14

7.6 Control Of Monitoring & Measuring Devices

Planning of the necessary monitoring and measuring devices takes place during the product's design and development phase, also taking into account aspects of environmental protection. The development status of the monitoring and measuring devices is checked in the product development project reviews. The development of test equipment begins with a determination of its specification, continues with its realization, registration and release, and ends with calibration and maintenance.

All equipment used for quality testing is registered, regularly calibrated and identified by the specified calibration bodies. This also applies to test equipment used to monitor plants and facilities with environmental relevance. The calibration results are reviewed and recorded. If the requirements are not met, suitable action is taken with regard to the test equipment and any products affected.
Software used to monitor and measure determined requirements is validated.

Evidence of product conformity to specified requirements is provided by suitable monitoring and measurement activities. Processes are established to ensure that monitoring and measurement are carried out and are consistent with requirements. Monitoring and measuring equipment is calibrated or verified at specific periods or before use against traceable standards. Monitoring and measuring equipment is adjusted or re-adjusted as necessary and identified as to its calibration status. Monitoring and measuring equipment is safeguarded against unauthorized adjustments and protected from damage and deterioration during use. Product that is verified with equipment found out of calibration is assessed and actions are taken as necessary to contain and correct the problem. Software used in monitoring and measurement is verified before use and reconfirmed as necessary.

References

Activity	Procedure
1. Determine monitoring and measurements to be undertaken and equipment needed to provide evidence of conformity	DSIN 7.3.01, DSN 5932, DSN 5933 and Appropriate Assembly Procedures
2. Establish processes to ensure monitoring and measurement can be carried out and are consistent with requirements	DSIN 7.3.01, DSN 5932, DSN 5933 and Appropriate Assembly Procedures
a) Shall ensure measuring equipment is calibrated or verified at specific periods or before use against traceable standards	DSN 5961 and Appropriate DSN 5500 Series Procedures
b) Shall ensure measuring equipment be adjusted or re-adjusted as necessary	DSN 5961 and Appropriate DSN 5500 Series Procedures
c) Shall ensure measuring equipment identified as to calibration status	DSN 5961 and Appropriate DSN 5500 Series Procedures
d) Shall ensure measuring equipment is safeguarded against unauthorized adjustments	DSN 5961 and Appropriate DSN 5500 Series Procedures
e) Shall ensure measuring equipment be protected from damage and deterioration during use	DSN 5961 and Appropriate DSN 5500 Series Procedures
3. Ensure that product verified with equipment found out of calibration is assessed and take actions as necessary	DSN 5961 and Appropriate DSN 5500 Series Procedures
4. Software used in monitoring and measurement is verified before use and reconfirmed as necessary	DSN 5102 and DSN 5913

8.0 Measurement, Analysis & Improvement 🕮

8.1 General

DSI monitors, measures, and analyzes processes to ensure product, process, and QMS conformity. The QMS is reviewed for the purpose of continual improvement. Methods for applying and selecting statistical techniques are identified by the Business Excellence System. A problem solving process has been implemented as indicated by the model in appendix "F".

See Appendix "F"

References

Activity	Procedure
1. Shall plan and implement the monitoring, measurement, analyze and improvement of processes	DSN 5904
a) Processes needed to demonstrate conformity of product	DSN 5904
b) Processes to ensure conformity of the quality management system	DSN 5904
c) Processes to continually improve the quality management system	DSN 5904
2. Determine applicable methods to include statistical techniques and the extent of their use	DSN 5962

8.2 Monitoring & Measurement

8.2.1 Customer Satisfaction

The degree to which customer requirements are met is an important measurement of the performance of the quality management system. To obtain and monitor this information, regular customer satisfaction analyses are carried out in the form of surveys, and complaints are systematically registered and analyzed. These surveys are conducted annually, the results analyzed and presented to the international decision-making groups. The actions determined on the basis of the results have an influence on the marketing plans and all affected processes.

References

Activity	Procedure
1. Shall monitor information relating to customer perception as to whether customer requirements have been met	BP9
2. Determine methods of obtaining information and how to use this information	DSN 5904

8.2.2 Internal Audit

DSI ensures the quality management system conforms to the standard as defined by the organization and is effectively implemented and maintained through internal auditing and product and process performance statistics. Audits are planned with consideration of the status and importance of the areas being audited. Previous audit results are considered when planning the audit schedule. Internal audit criteria, scope, frequency, and audit methods are defined. Auditors are selected and audits conducted to ensure objectivity and impartiality. Auditors will not audit their own work. Responsibilities and requirements for planning, conducting, reporting, and maintaining audit records are defined within the procedure.

References

Activity	Procedure
a) Ensures the quality management system conforms to the standard as defined by the organization	DSN 5911
b) Ensures the quality management system is effectively implemented and maintained	DSN 5911
1. Audits shall be planned with consideration of the status and importance of the areas being audited	DSN 5911
2. Previous audit results will be considered when planning	DSN 5911
3. Define the criteria, scope, frequency and ,methods of audits	DSN 5911
4. Select auditors and conduct of audits shall ensure objectivity and impartiality	DSN 5911
5. Auditors shall not audit their own work	DSN 5911
6. Define responsibilities and requirements for planning and conducting audits within the procedure	DSN 5911
7. Define reporting of audit results within the procedure	DSN 5911
8. Define maintaining of audit records within the procedure	DSN 5911

8.2.3 Monitoring & Measurement of Process

DSI applies suitable methods for monitoring, measuring, and taking corrective action on processes that do not achieved conformity. They demonstrate the ability of processes to achieve planned results and when necessary, take corrective action when planned results are not achieved.

References

Activity	Procedure
1. Shall apply suitable methods for monitoring and measuring processes	DSN 5904
2. Methods shall demonstrate the ability of processes to achieve planned results	DSN 5904
3. Shall take correction and corrective action when planned results are not achieved to ensure conformity	DSN 5917 and DSN 5918

The standard procedure for the introduction of new processes and significant changes to existing processes is the "Quality Improvement Process" (QIP) as indicated in appendix "G".

See Appendix "G"

8.2.4 Monitoring & Measurement of Product

DSI monitors and measures product characteristics in the various stages of the product realization process to verify that they have been met. DSI also monitors and measures at appropriate stages of product realization in accordance with the design plan. Records of acceptance criteria and persons authorizing the release of product are maintained. Release of product or service is not permitted until planned arrangements have been completed unless approval by relevant authority and / or customer is authorized.

References

Activity	Procedure
1. Monitor and measure characteristics of the product to verify requirements have been met	DSN 5933
2. Monitor and measure at appropriate stages of product realization in accordance with plan	DSN 5933
3. Maintain records of acceptance criteria	DSN 5933
4. Maintain records of person (s) authorizing release of product	DSN 5933
5. Release of product or service shall NOT proceed until planned arrangements have been completed UNLESS approved by relevant authority and / or customer	DSN 5933

8.3 Control Of Nonconforming Product

DSI has identified and documented the controls and related responsibilities and authorities for nonconforming material and product. Nonconforming material is corrected by taking action to eliminate the nonconformity, authorizing its use, release or acceptance under concession by relevant authority or customer, and controlled actions for scrapping. Records are maintained of nonconformities and actions to eliminate them. Nonconforming product that has been reworked is re-inspected to verify conformance to requirements. Actions are taken appropriately that are proportional to potential effects of nonconforming material discovered after delivery or use.

References

Activity	Procedure
1. Ensure product not conforming to product requirements is identified and controlled	DSN 5935
2. Controls and related responsibilities and authorities for nonconforming material shall be defined in a documented procedure	DSN 5935
a) Nonconforming material is dealt with by taking action to eliminate the nonconformity	DSN 5935
b) Nonconforming material is dealt with by authorizing it use, release or acceptance under concession by relevant authority and / or customer	DSN 5935
c) Nonconforming material is dealt with by scrapping	DSN 5935
3. Maintain records of nonconformities and actions taken	DSN 5935, DSN 5991 and Quality Records Matrix
4. Nonconforming product that has been reworked shall be re-inspected to verify conformance to requirements	DSN 5935
5. Take action appropriate to the effects or potential effects of nonconforming material discovered after delivery or use	DSN 5935

8.4 Analysis Of Data

DSI has determined the data to collect and analyzes that data to demonstrate suitability and effectiveness of the quality management system. Data also includes that generated as a result of monitoring and measurement of other relevant sources. The analysis of data relates to customer satisfaction, conformity to product requirements, characteristics & trends of processes & products including opportunities for preventive action, and data related to supplier activities.

References

Activity	Procedure
1. Determine data to collect to demonstrate suitability and effectiveness of the quality management system	DSN 5904
2. Collect and analyze data to demonstrate suitability and effectiveness of the quality management system	DSN 5904
3. Data shall include that generated as a result of monitoring and measurement or other relevant sources	DSN 5904
a) Analysis of data shall relate to customer satisfaction	DSN 5904
b) Analysis of data shall relate to conformity to product requirements	DSN 5904
c) Analysis of data shall relate to characteristics and trends of processes and products to include opportunities for preventive action	DSN 5904
d) Analysis of data shall relate to suppliers	DSN 5904

8.5 Improvement

8.5.1 Continual Improvement

The effectiveness of the quality management system is continually improved through the use of the quality policy, the quality objectives defined on the basis of the quality policy, the results of internal and external audits, the results of data analyses, corrective and preventive actions and the management review.

References

Activity	Procedure
1. Shall continually improve the effectiveness of the quality management system	Appendix A and G
2. Improvement is based on quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review	Appendix A and G

8.5.2 Corrective Action

DSI takes action to eliminate causes of nonconformities and to prevent recurrence based on the effects of the nonconformity. Documented procedures have been implemented for reviewing nonconformities (including customer complaints), determining the causes of nonconformities, evaluating the need for actions to ensure that nonconformities do not recur, determining and implementing actions needed, reviewing corrective actions, and for the control of records of the results of actions taken.

References

Activity	Procedure
1. Shall take action to eliminate causes of nonconformities to prevent recurrence based on the effects of the nonconformity	DSN 5918 and DSN 5935
a) Documented procedure for reviewing nonconformities to include customer complaints	DSN 5918, DSN 5935 and DSN 5952
b) Documented procedure for determining causes of nonconformities	DSN 5918 and DSN 5935
c) Documented procedure for evaluating need for action to ensure nonconformities do not recur	DSN 5918 and DSN 5935
d) Documented procedure for determining and implementing action needed	DSN 5918 and DSN 5935
e) Documented procedure for control of records of the results of actions taken	DSN 5918, DSN 5935, DSN 5991 and Quality Records Matrix
f) Documented procedure for reviewing of the corrective action taken	DSN 5115 and DSN 5918

8.5.3 Preventive Action

DSI determines actions that are needed to eliminate causes of potential nonconformities to prevent their occurrence and that preventive actions are appropriate for the effects of potential problems. Documented procedures have been implemented for determining potential nonconformities & their causes, evaluating the need for action to prevent nonconformities, determining & implementing needed actions, reviewing preventive action taken, and the control of records of the results of actions taken.

References

Activity	Procedure
1. Determine action needed to eliminate causes of potential nonconformities to prevent their occurrence.	DSN 5917
2. Preventive actions shall be appropriate to the effects of the potential problems	DSN 5917
a) Documented procedure for determining potential nonconformities and their causes	DSN 5917
b) Documented procedure for evaluating the need for action to prevent nonconformities	DSN 5917
c) Documented procedure to determine and implementing action needed	DSN 5917
d) Documented procedure for control of records of the results of actions taken	DSN 5917, DSN 5991 and Quality Records Matrix
e) Documented procedure for reviewing preventive action taken	DSN 5917

9.0 Appendices

9.1 APPENDIX "A"

VISION

Our Vision is to be a Major Source in North America for protection and detection product solutions and product services.

MISSION STATEMENT

Our Mission is to develop, produce and distribute products and services for detection of hazardous substances and for protection of human beings against these dangers.

"We Care for Your Safety"

VALUES

- Our Employees for their skills, innovation and creativity, and their involvement.
- Our mutually profitable relationships with our customers, distributors, and suppliers.
- Our reputation as a trusted and reliable source for protection and detection solutions for products and services.
- The Quality of Our Safety in our work and our Environment

QUALITY POLICY

" . . . to provide the highest quality products and services to our customers, with each employee responsible for providing products and services that are free of defects and meet all customer expectations,"

BREAKTHROUGH QUALITY OBJECTIVES

- Reduce the Cost of Quality
- Reduce failure rate of key products by 50%
- Achieve 95% on time delivery
- Balanced operating results (meeting quarterly sales & profit targets)

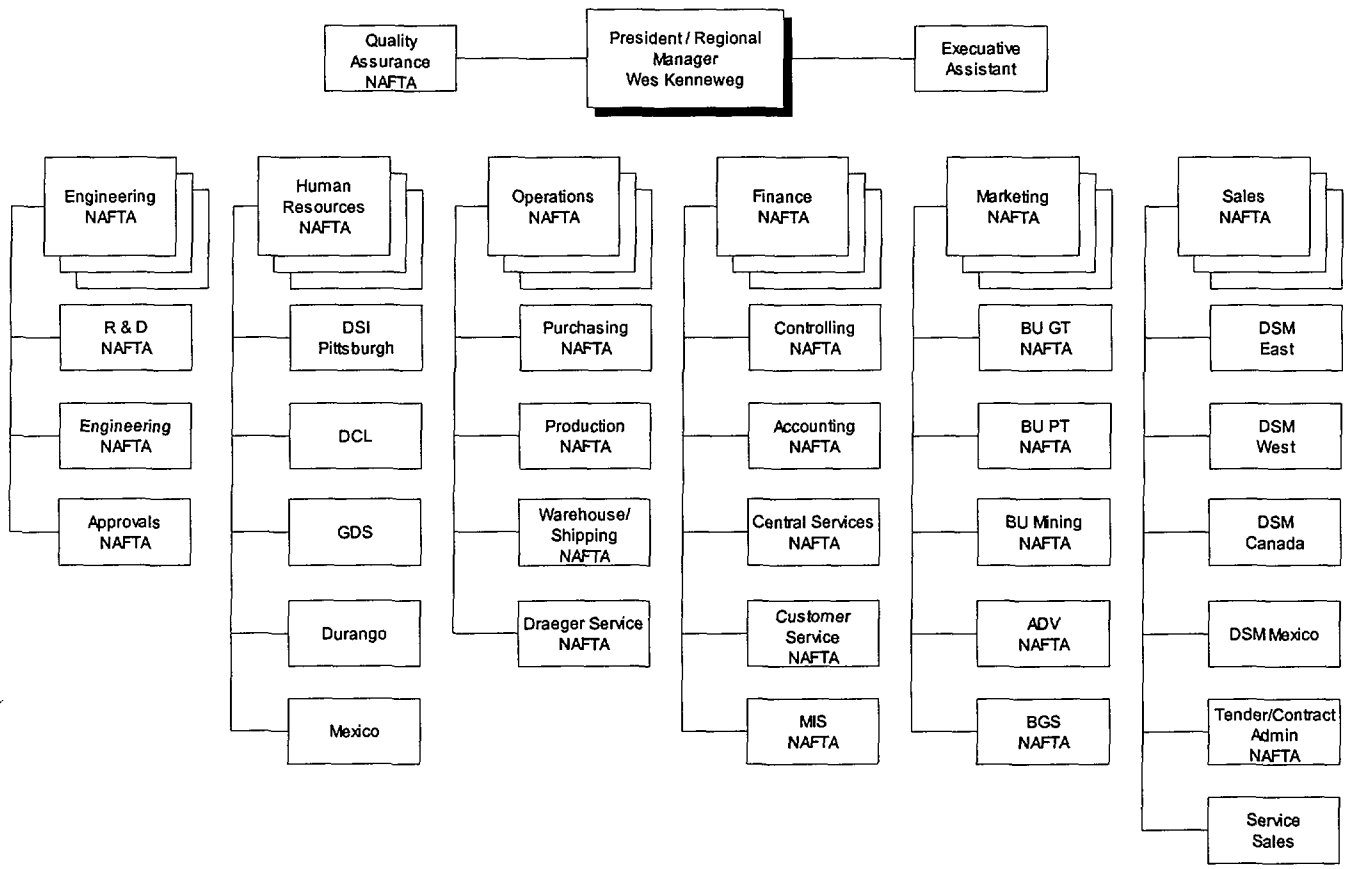
APPENDIX "A" continued

(2002)
Organizational Goals & Objectives

Meet or Exceed Profit Budget	2002 Quarterly
Meet Sales Quarterly Budget Targets:	2002 Quarterly
Meet mid year 55% Sales target	End 2nd Qtr 2002
Implement SAP Information Business System	Cut over 10/2002
Successful Registration to ISO 9001:2002	By 9/2002
Develop Micro Warn four Gas Unit	2002
Respond to Employee survey w/ BEST process	By March 2002
Implement NAFTA Inventory Hub	2002
On time Shipping Time for Stock Items:	Less than 24 hours
Inventory Turns:	3.5 turns
Monthly Shipment Accuracy (including serial #s)	99.25%
Continuous Improvement of BEST Initiatives:	Ongoing

9.2 APPENDIX "B" 🕮

Organizational Chart Draeger Safety Inc.



Issue Date
05/21/2002

9.3 APPENDIX "C" 🕮

Process Management

- Sales including order processing
- After sales including customer satisfaction & Service
- Operations including purchasing, production, & delivery
- Information Services including reporting & analysis
- Marketing
- Product development
- Quality Planning
- Training
- Design
- Production and Service
- Monitoring and Measurement
- Internal Audits

9.4 APPENDIX "D" 🕮

Quality Management Principles

Customer Focus

Constant customer focus is a prerequisite for our business success. We must meet and surpass our customer's needs, and anticipate future requirements. We gear the company's organization to our customers' requirements and regularly review customer satisfaction.

Leadership

Through our leadership, we provide our staff with clear role models. We set ambitious goals and instruct our staff in how to achieve these goals. We plan a strategy that will secure our company's future.

Staff Participation

Our employees work towards the company's goals and are involved in decision-making and process improvements.

Process Approach

We identify the external and internal customers and suppliers of our business processes, and make sure that our processes efficiently meet our customers' needs.

System-Based Management Approach

We ensure that sub-processes of our company interact effectively and achieve the company's overall objectives. We measure the success of our sub-processes and the overall success of the company.

Continuous Improvement

We set ambitious yet realistic goals, provide the tools needed to achieve these goals and ensure that the continuous improvement of our company is an integral part of our employees' work. In the Business Excellence courses we trained our staff in the necessary methods, and through ongoing problem solving and quality improvement processes we are further developing our entire company in all its departments.

Fact-Based Decision-Making

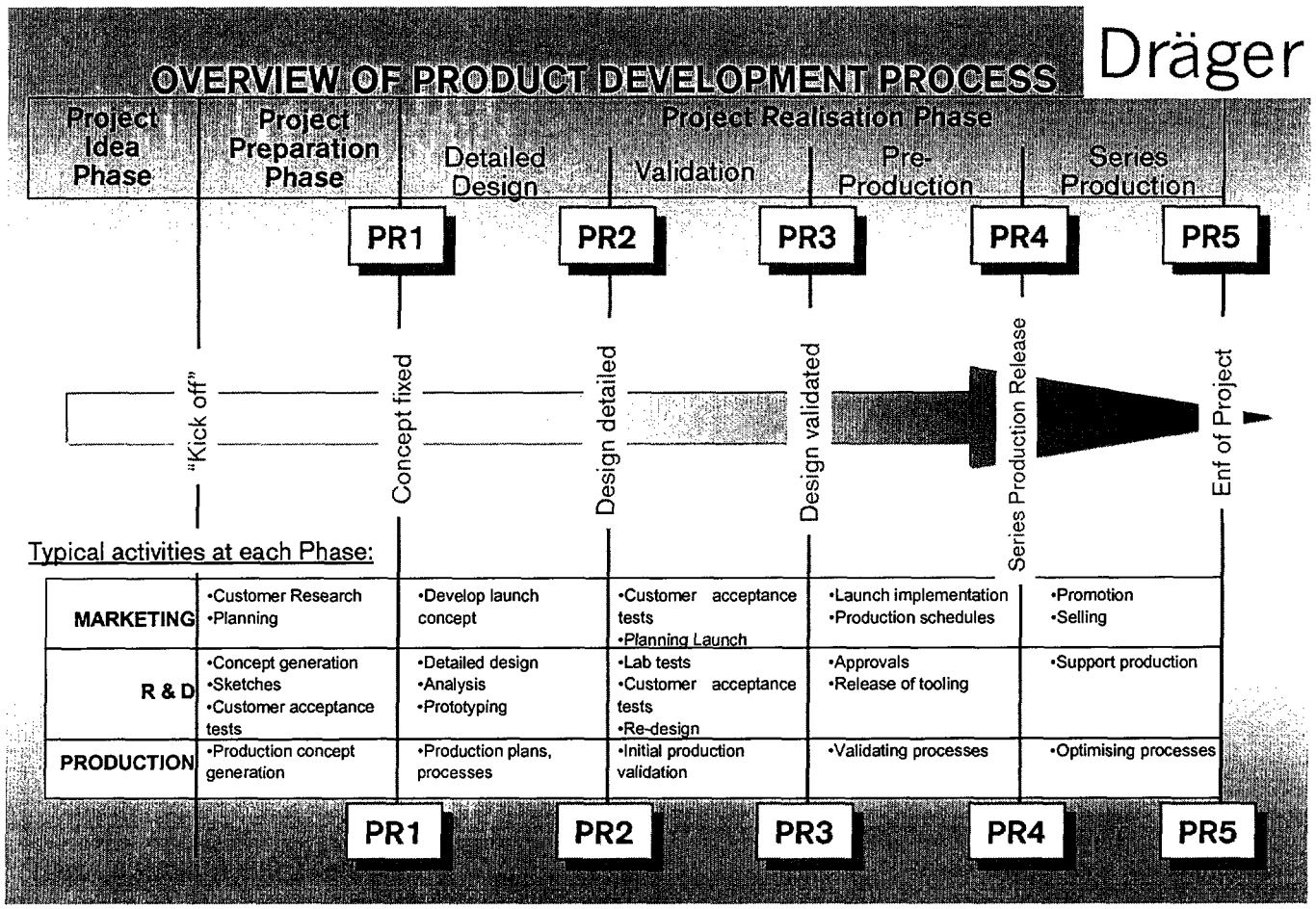
We base our decisions on data and information that we obtain and evaluate from reliable processes. From our measurement of process results and the satisfaction of our customers, we determine the necessary improvement actions.

Supplier Relations for Mutual Benefit

We are aware that we can only satisfy our customers if we involve our suppliers in these activities from the outset. We want to work together with our suppliers on a basis of trust so as to guarantee satisfaction of our customers.

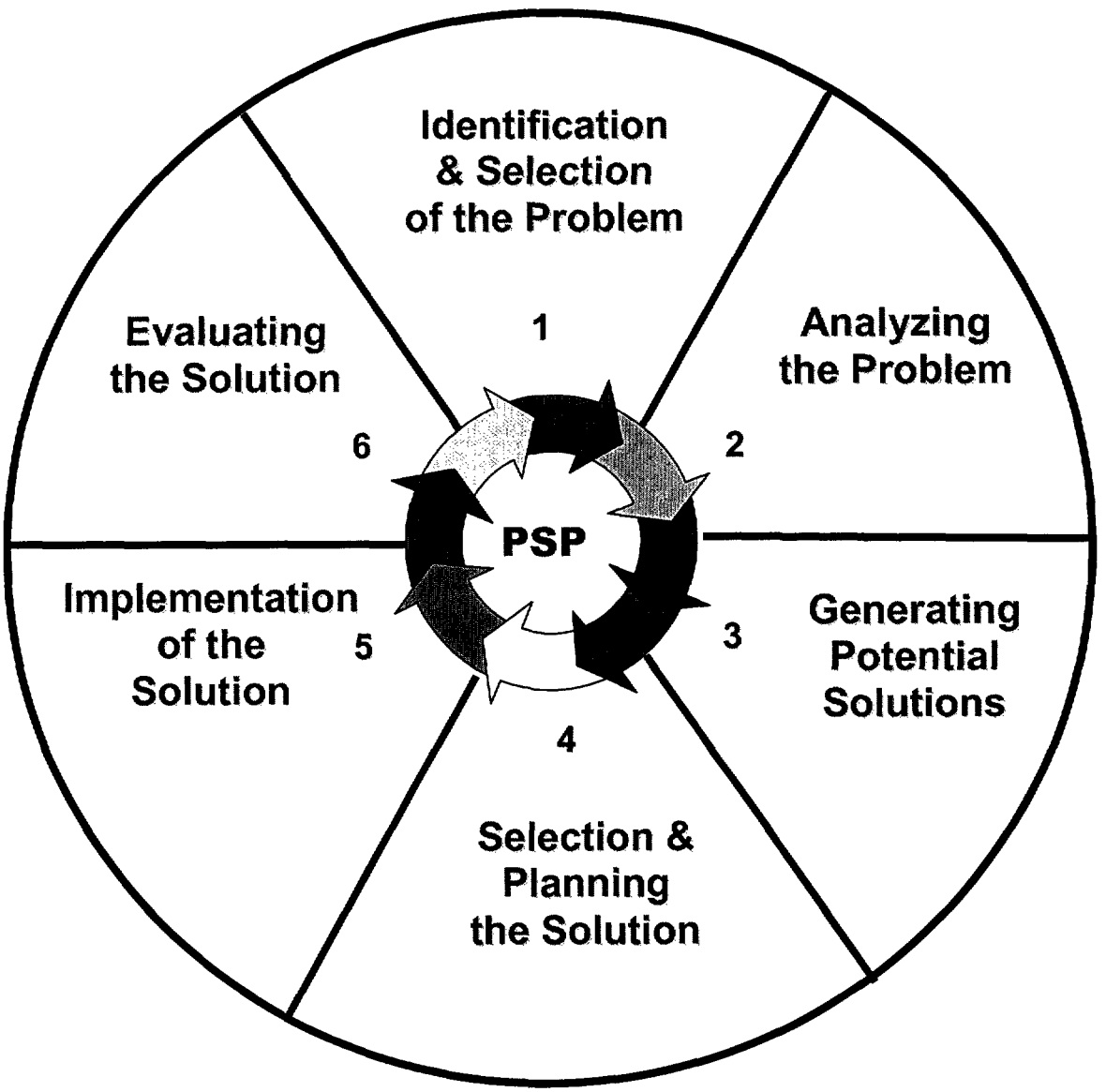
9.5 APPENDIX "E" 🕮

Overview of the Product Design & Development Process



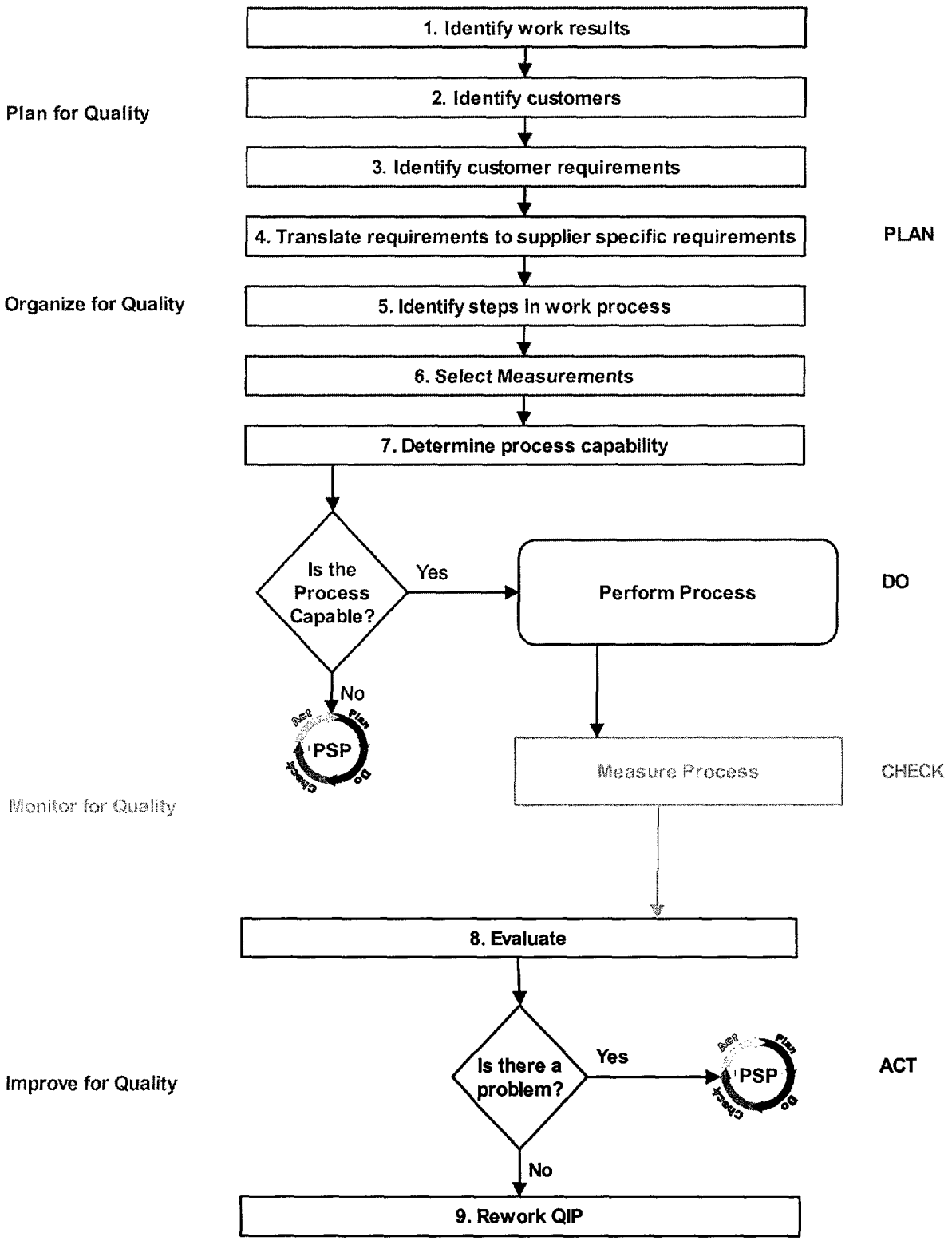
9.6 APPENDIX "F" 🕮

The Problem Solving Process



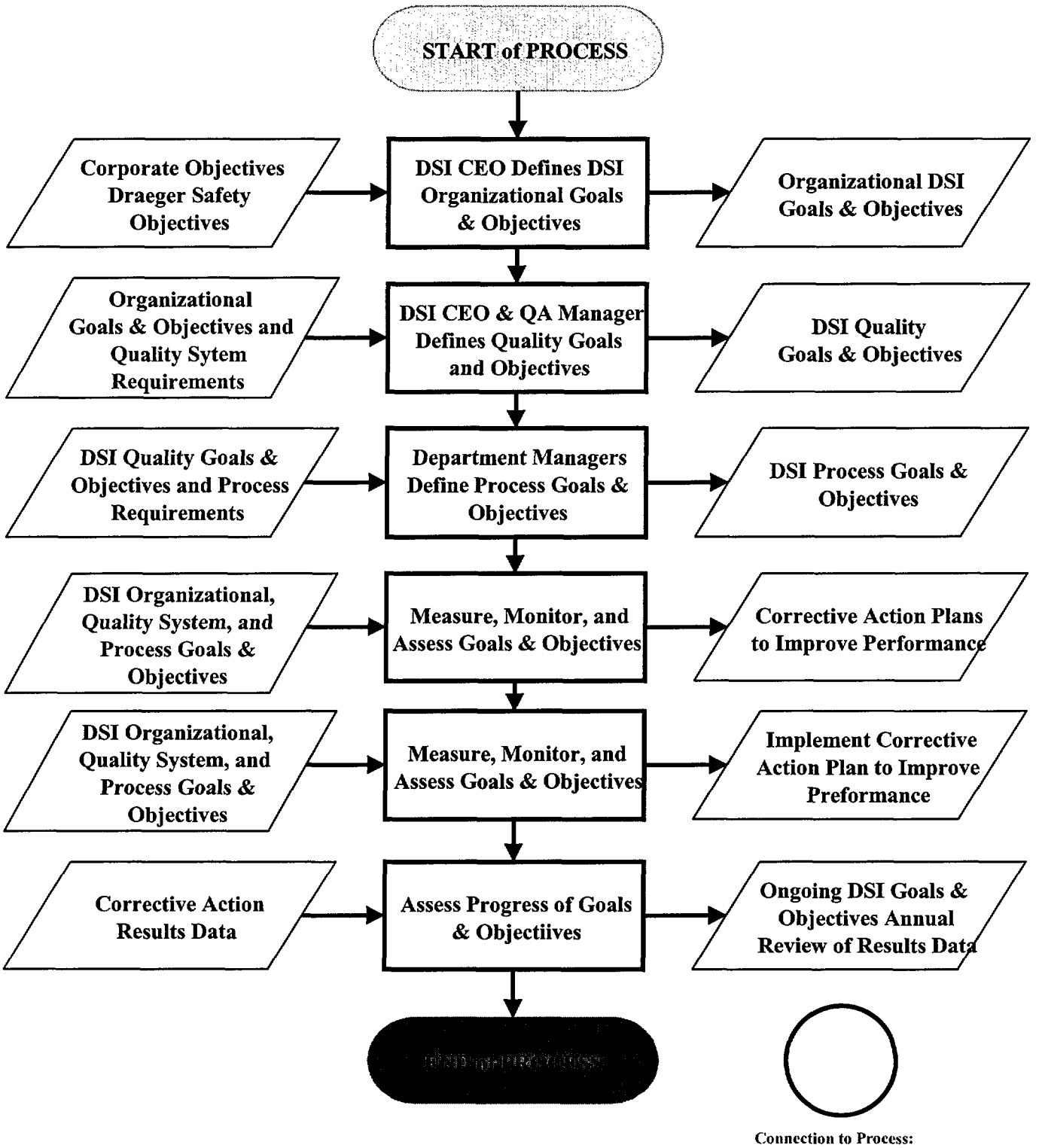
9.7 APPENDIX "G" 🕮

The Quality Improvement Process



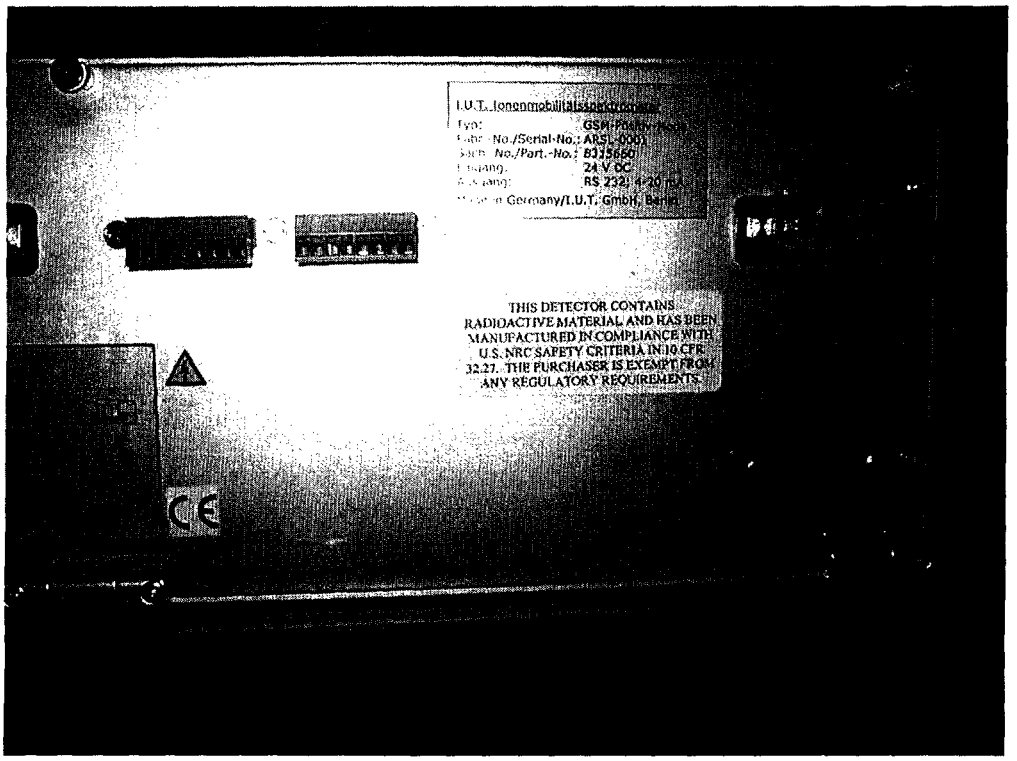
9.8 APPENDIX "H"

Planning Quality Objective Process
(Level "A")

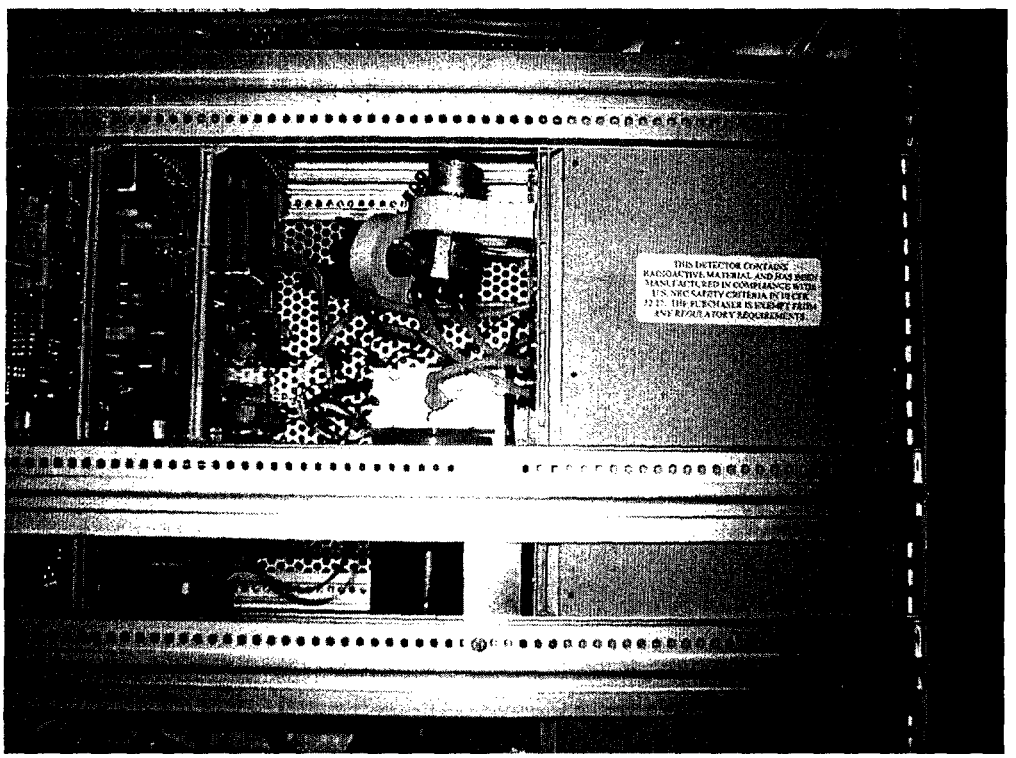


Connection to Process:

ATTACH H



Label on rear of IMS Unit



Label on detector unit