

EXPOSOLIDOS2003

Salón del manejo y ek Procesamiento de Materiales a Granel

Technical conferences

19 – 21 de Noviembre

Análisis de riesgos de explosión en la industria del polvo

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Risk analysis for Industries handling dusts

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RISK ANALYSIS FOR INDUSTRIES HANDLING DUSTS

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1 Risk Assessment

1.1 Used Method

The technical report "RASE-Project, Explosive Atmosphere: Risk Assessment of Unit Operations and Equipment" /1/ and the Work item (future EN Standard) No. 305083 of CEN TC305/WG4 "Methodology for risk assessment of non-electrical equipment for intended use in potentially explosive atmospheres" /2/ give examples for the application of the risk analysis and risk assessment. Both papers are using a method of the relative quantification that is a method of an assessment of the risks by comparative consideration. In this phase, the risk assessment helps to create a rational base for the explosion prevention and protective measures to be taken. Therefore, in most cases an additional arithmetical quantification is not necessary.

The above inductive analysis method is based on the US Military standard 882 /3/. This standard corresponds to the System-Safety-Concept, which was developed in the 50's for the aviation and space industry in the USA. This method was further developed and made perfect in the department risk engineering of the "Zürich" Insurance company /4/.

In practice risk analysis with a semi, quantitative character has been in use for a long time and worked satisfactorily /5/. As example of such risk assessments, which are based on technical expert knowledge and experiences of many years, is the hazard area classification for explosion protection. Today companies are using this method systematically from chemistry, pharmacy and food industry as well as from the metalworking industry. A substantial reason for this may be that this method is simply, handy and economical.

Once all the hazards have been identified, an estimate of the severity/impact of the possible harm, which can arise and the probability of the occurrence of each hazard has to be made in order to rank the risks. The severity/impact is ranked in four categories /5/ ranging from "catastrophic" to "insignificant" (Table 1) while the probability of an event occurring is expressed in six stages /5/ from "frequent" to "practically impossible" (Table 2). A risk-profile grid is drawn up /5/ in which the safety objective, e.g., the acceptable risk to be established by the risk analysis team in accordance with its management (or in line with the expected safety level) can be illustrated by a stepped line /5/, which is equal to the SAFETY OBJECTIVE (Fig. 1).

With the determined probability and the estimated severity/impact of an explosion, a risk profile grid (Fig. 1) can be made for the protection aim and the definable tolerable risk in respect of the expected safety level represented by a stepped characteristic line (black, bold).

Table 1. Semi-quantitative classification of severity/impact I assessment of an explosion
(With people and property for manufacturer; with people, environment and property for user)

Category of Severity/ Impact I	Description	
I (catastrophic)	People: Environment: Property:	Deaths or Long-term damage or > 10 million EURO; outage time of the installation: > 1 year.
II (critical)	People: Environment: Property:	Injuries, (unfit for more than 3 days) or Reversible damage or < 10 million EURO; outage time of the installation: months.
III (minor)	People: Environment: Property:	Slightly injured (unfit for maximal 3 days) or Damage in the plant area or < 2 million EURO; outage time of the installation: weeks.
IV (insignificant)	People: Environment: Property:	No injuries and No damage and < 0.5 million EURO; outage time of the installation: days.

Table 2. Semi-quantitative classification of the probability P of an explosion

Probability P	Description	Interpretation
A	more than once a year	frequent
B	once a year	often
C	once in 5 years	occasional
D	once in 30 years	rare
E	once in 100 years	improbable
F	once in 1000 years	practically impossible

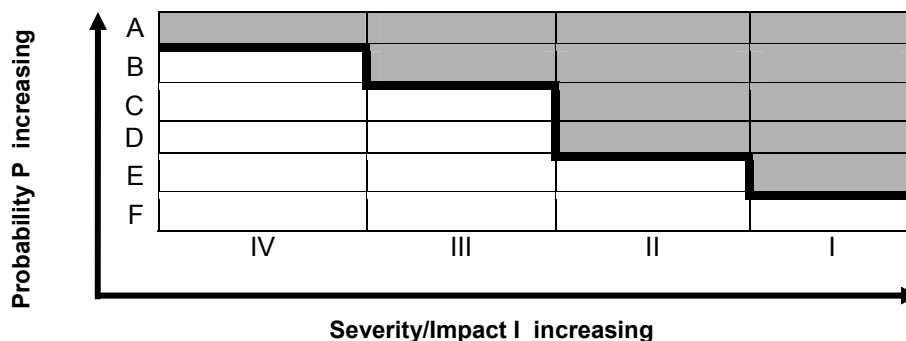


Figure 1. Risk-profile grid with safety objective (stepped line)

After careful assessment, the risks below the protection line (weight area) are within the protection aim and therefore, they are accepted as tolerable. The risks

above or on the right side of the protection line (grey area), are not tolerable and require protective measures. These risks are to be eliminated according to their individual priorities with the target of getting them into the tolerable area.

The risk-profile grid forms the basis for the risk accomplishment.

1.2 Residual risk

At first, the manufacturer has to identify the ultimate remaining risk from his point of view. There are no general valid criteria for the acceptance of the remaining risk. Beside the pure technical aspects, it is also important to take into account economical, operational, environmental and social political aspects. Therefore, the assessment of the remaining risk (residual risk) can demand further measures. In the final analysis, this can be the cancellation of the intended process.

The residual risk comprises:

- intentionally accepted risks
- falsely assessed risks
- unrecognized risks.

Summarizing, a project can be accepted as safe from the technical point of view, if:

- a complete risk assessment has been carried out,
- the actual available knowledge and the scientific know-how have been optimally used,
- all safety measures correspond to national laws, to the state-of-the-art, to the realizations of the carried out risk assessment as well as to the applicable technical rules and to safety instructions.

1.3 Time and occasion of the risk assessment

1.3.1 Manufacturer

In ideal conditions, the risk assessment of the manufacturer for new machines or plants already starts during the research phase and is then continued through all further phases - like development, trial in an experimental station and at final design /6/.

Risk analysis is carried out on existing processes:

- to improve the level of safety,
- to include new experience (in-house or external), and/or
- to re-evaluate residual risks.

If the possibility of new hazards exists, e.g., in case of:

- modification of process or plant,
- change of equipment/transfer of production,
- change of starting materials (different source), and/or
- repairs.

1.3.2 User

The user has to carry out his own risk assessment (regarding the protective measures and the residual risk) based on the statements of the manufacturer and made in the designated applications of his fluid bed unit /7/.

First of all, it has to be guaranteed that the application range provided by the manufacturer agrees with the operational situation (explosion hazard areas) and that it is possible to operate the machine according to the intended use. If the residual risk indicated by the manufacturer is not acceptable for the actual application, either the user has to inform the manufacturer that he has to take additional measures to further reduce the consequences of damage or the user himself has to carry out corresponding measures on his own. As an example, if an explosion pressure venting in the working area is not acceptable, it is either required to take additional design measures (vent ducts) or the installation site has to be changed (outdoor installation).

The user shall carry out a risk assessment prior to machine commissioning. This takes into account the statements of the manufacturer regarding the intended use and the machine-specific residual risk. Contrary to the risk assessment of the manufacturer, the risk assessment of the user considers additional hazards given by operational boundary conditions (installation site, interfaces to adjacent machines, etc.).

The user has to repeat the risk assessment whenever there are changes to the machine, of the process or to the operational conditions. This is particularly required:

- if there is the possibility of new hazards, for example in case of
 - changes of the procedure
 - changes or repairs to the installation
 - changes in raw materials (origin, form, specifications)
- to introduce new experiences (internal or outside)
- to verify and improve the safety level periodically.

The user has to ensure that the limiting values (product characteristics) listed in Table 2 are followed and observed. The owner has to check and to certify this procedure in a suitable way (inspection reports of the supplier completed according to agreed and approved test procedures or measurements with certified test equipment). It is recommended that samples are stored for traceability purposes.

1.4 Teamwork

Only the interdisciplinary cooperation of experts ensures that

- individual experiences have influence on the risk assessment,
- the dangers can be considered and assessed from various points of view,
- possible disadvantages of suggested measures can be recognized on time,
- decisions at one's own discretion can be more on the safe side during the risk assessment.

2 Risk Assessment Example for a Fluid Bed Granulator

2.1 General

To give an example for a fluid bed granulator a risk assessment is carried out using all relevant standards, guidelines, technical reports and literatures /1,2,5, 8...11/.

2.2 Intended Use

Fluid bed granulation is a very common industrial process for mixing, humidifying, agglomerating and the drying of powdery substances. The actual example describes a batch processing system.

2.3 Description of the system (machine, product, process)

The powder placed into the fluid bed granulator is whirled up with conditioned air. The resulting vortex distribution allows an intensive airflow around the individual powder particles. This effects a very extensive contact surface of the powder with the sprayed liquid and with the drying air. If the powder has been humidified, the particles stick together. The grain spectrum will be magnified by this agglomeration process. Figure 1 shows a scheme of the fluid bed granulator. The fan (11) sucks fresh air through an inlet air-handling unit (1) and then through the fluid bed granulator. In the inlet air-handling unit the process air is cleaned and heated up to a temperature dependent on the process. The necessary volume flow is controlled by the outlet air butterfly valve (9) to get the right vortex distribution (fluidized bed) depending on product quantity and product consistency.

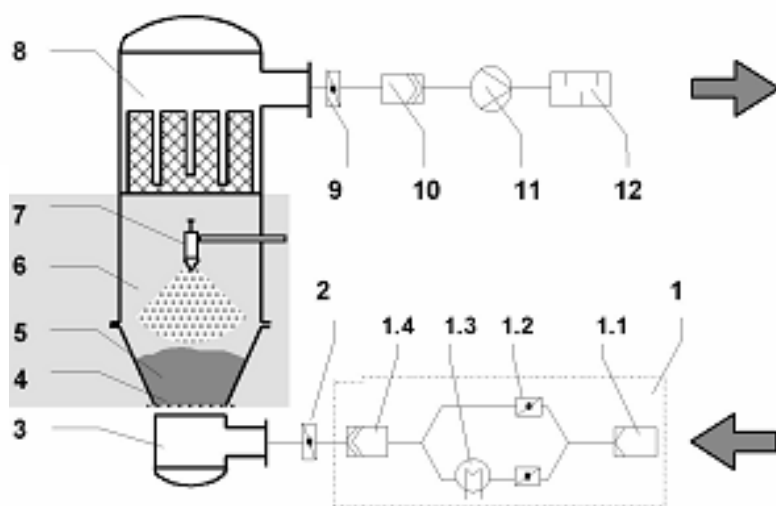


Figure 1. Scheme for the intended use of the machine areas

1	inlet air handling unit	3	Plenum chamber	9	Outlet air butterfly valve
1.1	Pre-filter	4	Sieve bottom	10	Safety filter (police filter)
1.2	Mixing louvers	5	Product container	11	Fan
1.3	Heat exchanger	6	Spraying/vortex zone	12	Silencer
1.4	After filter	7	Spraying nozzle		
2	Inlet butterfly valve	8	Filter housing with product retaining filter		

During the spraying phase liquid is sprayed onto the solid particles by a spraying nozzle (7) fixed centrally above the product. The spraying nozzle atomizes the liquid into small droplets with compressed air. The size of the droplets is determined by the nozzle type, the pressure of the atomizing air and the characteristics of the liquid. The temperature of the process depends on the spray rate in respect to the product humidity and the inlet air conditions. The evaporation of the liquid creates a temperature decrease in the fluid bed granulator. Filter bags (8) above the spray and vortex zone (6) avoid a loss of product by a cleaning process in which the filters are cyclically shaken. Behind the filter bags the air passes through a safety filter (10), (a so-called police filter (filter cassette)), through the fan (11) and lastly through the silencer (12) on the pressure side of fan before the air is blown out. If there is a rupture of the filter bags, the police filter protects the environment and guarantees the avoidance of an explosive dust-air-mixture in the area of the fan.

All machine components (except the filters and seals) are made mainly of stainless steel.

The relevant machine and process conditions are listed in Table 1.

Table 1. Relevant machine and process conditions

Machine conditions (refer to Fig. 1)	
Total volume of the machine (3 to 8)	: 3.6 m ³
Volume of the vortex area (5 and 6)	: 2.1 m ³
Height/diameter ratio	: 2.2
Pressure shock resistance of the machine	: 2 bar (overpressure)
Material of product retaining filter	: PE fabric, isolating (non-conducting)
Volume flow of the fan (maximum value)	: 5'040 m ³ · h ⁻¹
Diameter of inlet air duct	: 300 mm
Diameter of outlet air duct	: 300 mm
Sieve bottom (4)	: perforated plate or wire mesh (100 µm)
Spraying nozzle, pneumatic (7)	: binary nozzle (air, liquid)
Materials of the machine	: stainless steel
Air heating unit (heat exchanger) (1.3)	: electric-powered; 140 kW
Installation conditions (application)	: no zone (no Ex-hazardous area)
Process conditions	
Process pressure (absolute)	: 900 mbar up to 1,013 mbar
Air inlet temperature	: ≤ 120 °C
Spraying liquid	: water

Table 2 summarizes the safety data of those products which have to be observed and followed by the owner and which are according to the designated application of the fluid bed granulator.

Table 2. Safety characteristics/parameters of the designated products /12,13/

Dust Layers	
Combustibility class CC at 20°C and 100°C	: ≤ 3
Smoldering point	: > air inlet temperature
Minimum ignition temperature MIT _{5mm} of a dust layer of 5 mm thickness	: ≥ 250 °C
Auto-ignition temperature	: > air inlet temperature in °C
Volume resistivity	: > 1000 Ohm m
Spontaneous decomposition capability	: no

Table 2. Continuing: Safety characteristics/parameters of the designated products

Dust clouds	
Minimum ignition temperature MIT of the dust cloud	: ≥ 350 °C
Temperature related minimum ignition energy MIE (without inductivity)	: ≥ 10 mJ
Maximum explosion overpressure P_{max}	: ≤ 10 bar
Maximum explosion constant K_{max}	: ≤ 300 bar·m·s ⁻¹
Dust explosions class St	: ≤ 2
Miscellaneous	
Flammable solvents within the processing product	: no
Reaction with water	: no
Air sensitivity and photosensitivity	: no
Toxicity	: no

2.4 Function/State Analysis

Table 3 represents the analysis of function and state of a fluid bed granulator.

Table 3. Analysis of function and state of a fluid bed granulator

Machine operations	Energies/Operating conditions	Physical characteristics of the products
Manual charging of the product to be processed	Environmental conditions	Dry powder and air
↓		
Heating up of product	Max. product temperature: 120 °C Max. inlet air temperature: 120 °C Operating pressure: \leq ambient pressure	Dry powder and air
↓		
Spraying the product with water	Max. product temperature: 120 °C Max. inlet air temperature: 120 °C Operating pressure: \leq ambient pressure	Water drops/steam, powder and air
↓		
Drying the aqueous product with a subsequent cooling process	Max. product temperature: 120 °C Max. inlet air temperature: 120 °C Operating pressure: \leq ambient pressure	Steam, granulated powder and air
↓		
Manual discharging of the product	Max. product temperature: 120 °C Operating pressure: \leq ambient pressure	Granulated powder and air
↓		
Storage of the product	Room temperature, ambient pressure	

2.5 Hazard identification

2.5.1 Hazard area classification

Based on the likelihood of the formation of potentially explosible dust-air mixtures the areas and therefore the zones can be designated according to the following Table 4 /9, 14/.

Table 4. Designation of dust Zones inside/outside of the equipments (Fig. 2)

Equipment	Zone
Interior of fluid bed granulator	
Inside: Continuously/frequently present of dust cloud.	20
Outside: Secondary grade of release; 1m from the edge of the source and extending down to the next solid floor.	22
Outlet air section up to safety filter (1, 7,8,9 Fig. 1)	
Inside: Occasionally present of dust cloud (during filling/emptying)	21
Outside: No dust release.	NZ
Outlet air section after the safety filter (10 , 11 Fig.1)	
Inside: For a short period only presence of dust cloud.	22
Outside: No dust release.	NZ
Inlet air section up to after filter (1.4 Fig.1)	
Inside: Occasionally present of dust cloud (during filling/emptying)	21
Outside: No dust release.	NZ

Figure 2 shows the hazard area classification in the interior and the close vicinity of a fluid bed granulator including the inlet and outlet air sections.

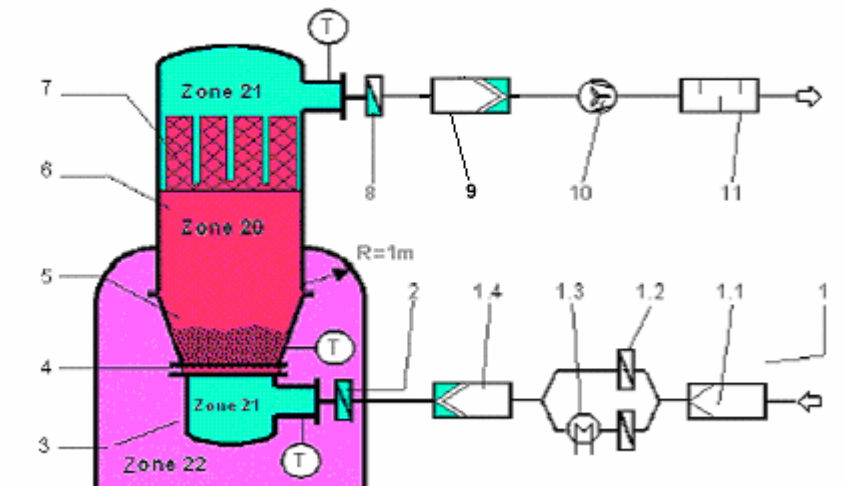


Figure 2. Zone partitioning inside and outside of the machine according to the intended designated application

1	inlet air handling unit	2	Inlet butterfly valve	7	Filter housing with product retaining filter
1.1	Pre-filter	3	Plenum chamber	8	Outlet air butterfly valve
1.2	Mixing louvers	4	Sieve bottom	9	Safety filter (police filter)
1.3	Heat exchanger	5	Product container	10	Fan
1.4	After filter	6	Spraying/vortex zone	11	Silencer

2.5.2 Ignition Sources

Tables 4 to 7 subsequently examine the individual machine sections for the existence of effective ignition sources (EN 1127-1 /9/) and their expected probability of occurrence /15...18/.

Table 4. List of the ignition sources for the interior of the fluid bed granulator

Pos.	possible	available	effective	Ref.
1	Hot surfaces	yes	Yes – can give sufficient energy	4.1
2	Flames and hot gases (including hot particles)	yes	Yes – can give sufficient energy	4.2
3	Mechanically generated sparks	no		
4	Electrical apparatus	yes	Yes – can give sufficient energy	4.4
5	Stray electric currents and cathodic corrosion protection	no		
<i>Static electricity:</i>				
6a	Corona discharge	yes	No – too little energy	
6b	Brush discharge	yes	No – too little energy	
6c	Propagating brush discharge	yes	Yes – can give sufficient energy	4.6c
6d	Conical pile discharge	no		
6e	Spark discharge	yes	Yes – can give sufficient energy	4.6e
7	Lightning	no		
8	Electromagnetic waves (RF) $10^4 - 3 \times 10^{12}$ Hz	no		
9	Electromagnetic waves $3 \times 10^{11} - 3 \times 10^{15}$ Hz	no		
10	Ionizing radiation	no		
11	Ultrasonics	no		
12	Adiabatic compression and shock waves	no		
13	Exothermic reactions and self-ignition of dusts	yes	Yes – can give sufficient energy	4.13

"No" in the third column means that this ignition source does not occur in this actual system.

"No" in the fourth column means that this ignition source is not effective in this actual examined system. Finally, the last column (Ref.) marks the remaining effective ignition sources for this example. Reference is made to each of these numbers in the following chapters.

Table 5. List of the ignition sources for the outlet air section between product retaining filter and police filter of the fluid bed granulator

Pos.	possible	available	effective	Ref.
1	Hot surfaces	yes	Yes – can give sufficient energy	5.1
2	Flames and hot gases (including hot particles)	yes	Yes – can give sufficient energy	5.2
3	Mechanically generated sparks	no		
4	Electrical apparatus	no		
5	Stray electric currents and cathodic corrosion protection	no		
<i>Static electricity:</i>				
6a	Corona discharge	yes	No – too little energy	
6b	Brush discharge	yes	No – too little energy	
6c	Propagating brush discharge	yes	Yes – can give sufficient energy	5.6c
6d	Conical pile discharge	no		
6e	Spark discharge	yes	Yes – can give sufficient energy	5.6e
7	Lightning	no		
8	Electromagnetic waves (RF) $10^4 - 3 \times 10^{12}$ Hz	no		
9	Electromagnetic waves $3 \times 10^{11} - 3 \times 10^{15}$ Hz	no		
10	Ionizing radiation	no		
11	Ultrasonics	no		
12	Adiabatic compression and shock waves	no		
13	Exothermic reactions and self-ignition of dusts	yes	Yes – can give sufficient energy	5.13

Table 6. List of the ignition sources for the outlet air section after the police filter of the fluid bed granulator

Pos.	possible	available	effective	Ref.
1	Hot surfaces	yes	Yes – can give sufficient energy	6.1
2	Flames and hot gases (including hot particles)	yes	Yes – can give sufficient energy	6.2
3	Mechanically generated sparks	yes	Yes – can give sufficient energy	6.3
4	Electrical apparatus	no		
5	Stray electric currents and cathodic corrosion protection	no		
<i>Static electricity:</i>				
6a	Corona discharge	yes	No – too little energy	
6b	Brush discharge	yes	No – too little energy	
6c	Propagating brush discharge	yes	Yes – can give sufficient energy	6.6c
6d	Conical pile discharge	no		
6e	Spark discharge	yes	Yes – can give sufficient energy	6.6e
7	Lightning	no		
8	Electromagnetic waves (RF) $10^4 - 3 \times 10^{12}$ Hz	no		
9	Electromagnetic waves $3 \times 10^{11} - 3 \times 10^{15}$ Hz	no		
10	Ionizing radiation	no		
11	Ultrasonics	no		
12	Adiabatic compression and shock waves	no		
13	Exothermic reactions and self-ignition of dusts	yes	Yes – can give sufficient energy	6.13

Table 7. List of the ignition sources for the inlet air section of the fluid bed granulator

Pos.	possible	available	effective	Ref.
1	Hot surfaces	yes	Yes – can give sufficient energy	7.1
2	Flames and hot gases (including hot particles)	yes	Yes – can give sufficient energy	7.2
3	Mechanically generated sparks	no		
4	Electrical apparatus	yes	Yes – can give sufficient energy	7.4
5	Stray electric currents and cathodic corrosion protection	no		
<i>Static electricity:</i>				
6a	Corona discharge	yes	No – too little energy	
6b	Brush discharge	yes	No – too little energy	
6c	Propagating brush discharge	no		
6d	Conical pile discharge	no		
6e	Spark discharge	yes	Yes – can give sufficient energy	7.6e
7	Lightning	no		
8	Electromagnetic waves (RF) $10^4 - 3 \times 10^{12}$ Hz	no		
9	Electromagnetic waves $3 \times 10^{11} - 3 \times 10^{15}$ Hz	no		
10	Ionizing radiation	no		
11	Ultrasonics	no		
12	Adiabatic compression and shock waves	no		
13	Exothermic reactions and self-ignition of dusts	yes	Yes – can give sufficient energy	7.13

2.5.3 Hazard identification

With the probability of the occurrence of explosible dust-air-mixtures (given by the zones 20 to 22) and with the probability of the occurrence of effective ignition sources it is possible to assess the probability of an explosion for the machine sections in question (Table 8).

Table 8. Listing of the hazard identification for the interior of the fluid bed granulator FBG

Unit	Explosive atmosphere		Effective ignition source		
	Type	Zone	Ref.	Cause	Likelihood
Interior of the FBG	Dust-air-mixture	20	4.1	Too hot air inlet temperature	during rare malfunction
			4.2	Too hot air inlet temperature	during rare malfunction
			4.4	Uncertified devices in use	during rare malfunction
			4.6c	Isolating coatings, sticky layers	during rare malfunction
			4.6e	The earthing is no longer effective	during malfunction
			4.13	Too hot air inlet temperature	during rare malfunction
Outlet air section of the FBG (7 to 9, Fig.1)	Dust-air-mixture	21	5.1	Too hot air inlet temperature	during rare malfunction
			5.2	Too hot air inlet temperature	during rare malfunction
			5.6c	Isolating coatings, sticky layers	during rare malfunction
			5.6e	The earthing is no longer effective	during malfunction
			5.13	Too hot air inlet temperature	during rare malfunction
Outlet air section of FBG (10 and 11 Fig.1)	Dust-air-mixture	22	6.1	Too hot air inlet temperature	during rare malfunction
			6.2	Too hot air inlet temperature	during rare malfunction
			6.3	Mechanical failure of the fan	during rare malfunction
			6.6c	Isolating coatings, sticky layers	during rare malfunction
			6.6e	The earthing is no longer effective	during malfunction
			6.13	Too hot air inlet temperature	during rare malfunction
Inlet air section of FBG (between after filter 1.4, and sieve bottom 4, Fig. 3)	Dust-air-mixture	21	7.1	Too hot air inlet temperature	during rare malfunction
			7.2	Too hot air inlet temperature	during rare malfunction
			7.4	Uncertified devices in use	during rare malfunction
			7.6e	The earthing is no longer effective	during malfunction
			7.13	Too hot air inlet temperature	during rare malfunction

2.6 Risk Estimation

For each hazardous event referred in the hazard identification, the probability and severity/impact of each risk (Table 9 has been estimated using criteria given in Tables 1 and 2.

This first risk estimation does not take into account any preventive and protective measures!

Table 9. Dangers, causes probability and impact for the fluid bed granulator FBG

Ref.	Unit	Effective ignition source	Cause	Probability	Event	Impact
4.1	Inside fluid bed granulator (Zone 20)	Hot surface	Too hot air inlet temperature	D	Explosion	I
4.2		Flames and hot gases	Too hot air inlet temperature	D	Explosion	I
4.4		Electrical apparatus	Short circuit of an electrical apparatus	C	Explosion	I
4.6c		Static electricity: propagating brush discharge	Isolating coatings, sticky layers	C	Explosion	I
4.6e		Static electricity: spark discharge	The earthing is no longer effective	C	Explosion	I
4.13		Exothermic reaction and self-ignition of dust	Too hot air inlet temperature and sticky layers	D	Explosion	I
5.1	Outlet air section between product retaining filter and police filter (Zone 21)	Hot surface	Too hot air inlet temperature	E	Explosion	I
5.2		Flames and hot gases	Too hot air inlet temperature	E	Explosion	I
5.6c		Static electricity: propagating brush discharge	Isolating coatings, sticky layers	E	Explosion	I
5.6e		Static electricity: spark discharge	The earthing is no longer effective	D	Explosion	I
5.13		Exothermic reaction and self-ignition of dusts	Too hot air inlet temperature and sticky layers	E	Explosion	I
6.1	Outlet air section after police filter (Zone 22)	Hot surface	Too hot air inlet temperature	F	Explosion	II
6.2		Flames and hot gases	Too hot air inlet temperature	F	Explosion	II
6.3		Mechanically generated sparks	Mechanical failure of the fan	C	Explosion	II
6.6c		Static electricity: propagating brush discharge	Isolating coatings, sticky layers	F	Explosion	II
6.6e		Static electricity: spark discharge	The earthing is no longer effective	E	Explosion	II
6.13		Exothermic reaction and self-ignition of dusts	Too hot air inlet temperature and sticky layers	F	Explosion	II
7.1	Inlet air section up to after filter (Zone 21)	Hot surface	Too hot air inlet temperature	F	Explosion	I
7.2		Flames and hot gases	Too hot air inlet temperature	F	Explosion	I
7.4		Electrical apparatus	Short circuit of an electrical apparatus	D	Explosion	I
7.6e		Static electricity: spark discharge	The earthing is no longer effective	C	Explosion	I
7.13		Exothermic reaction and self-ignition of dusts	Too hot air inlet temperature and sticky layers	E	Explosion	I

The risk level shown in Figure 4 has been determined using the risk-profile grid shown in Figure 1.

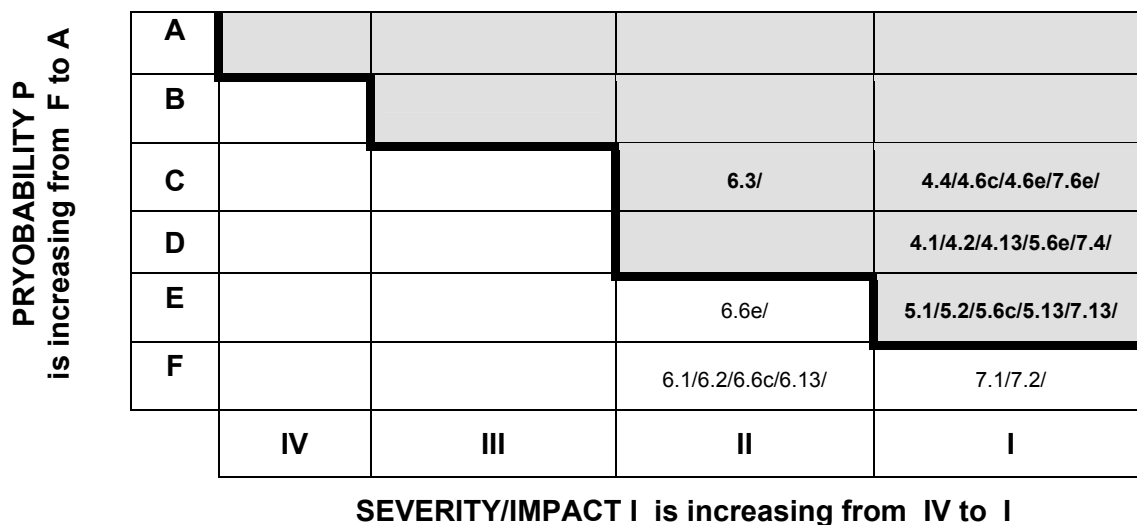


Figure 4. Risk profile for the fluid bed granulator

2.7 Risk Reduction Measures

Table 10 summarizes the planned safety measures, which are going to reduce the probability and/or the effect of the units, which risks shown in Figure 4 are above of the safety-objective line (gray area), and however, are not acceptable.

Table 10. Catalogue of planned safety measures for the units, which risks (Fig. 2, gray area) are above of the safety-objective line (P = Probability, I = Impact)

Ref.	Unit	Effective ignition source	Risk		Planned safety measures
			P	I	
4.1	Inside fluid bed granulator (Zone 20)	Hot surfaces	D	I	Installation of temperature monitoring systems.
4.2		Flames and hot gases	D	I	
4.4		Electrical apparatus	C	I	Only installation of certified electrical apparatus.
4.6c		Static electricity: propagating brush discharge	C	I	Avoiding sticky layers by periodical check/cleaning.
4.6e		Static electricity: spark discharge	C	I	Installation of an earthing monitoring system.
4.13		Exothermic reaction and self-ignition of dusts	D	I	Installation of temperature monitoring systems. Avoiding sticky layers by periodical check/cleaning.
5.1	Outlet air section between product retaining filter and police filter (Zone 21)	Hot surfaces	D	I	Installation of temperature monitoring systems.
5.2		Flames and hot gases	D	I	
5.6c		Static electricity: propagating brush discharge	C	I	Avoiding sticky layers by periodical check/cleaning.
5.6e		Static electricity: spark discharge	C	I	Installation of an earthing monitoring system.
5.13		Exothermic reaction and self-ignition of dusts	D	I	Installation of a temperature monitoring system. Avoiding sticky layers by periodical check/cleaning.

Table 10. Continuing: Catalogue of planned safety measures for the units, which risks (Fig. 2, gray area) are above of the safety-objective line (P = Probability, I = Impact)

Ref.	Unit	Effective ignition source	Risk		Planned safety measures
			P	I	
6.3	Outlet air section after police filter (Zone 22)	Mechanically generated sparks	C	II	Only installation of certified fan (3D).
7.4	Inlet air section up to after filter (Zone 21)	Electrical apparatus	D	I	Only installation of certified electrical apparatus.
7.6e		Static electricity: spark discharge	C	I	Installation of an earthing monitoring system.
7.13		Exothermic reaction and self-ignition of dusts	E	I	Installation of a temperature monitoring system. Avoiding sticky layers by periodical check/cleaning.

Table 11 summarizes these types of safety measures, which guarantees that the units having acceptable risks (Figure 4, white area) cannot be developed to a possible hazard.

Table 11. Catalogue of safety measures for the units, which risks (Figure 4, white area) are acceptable (P = Probability, I = Impact)

Ref.	Unit	Effective ignition source	Risk		Planned safety measures
			P	I	
6.1	Outlet air section after police filter (Zone 22)	Hot surfaces	F	II	Installation of temperature monitoring systems.
6.2		Flames and hot gases	F	II	
6.6c		Static electricity: propagating brush discharge	F	II	Avoiding sticky layers by periodical check/cleaning.
6.6e		Static electricity: spark discharge	E	II	Installation of an earthing monitoring system.
6.13		Exothermic reaction and self-ignition of dusts	F	II	Installation of temperature monitoring systems. Avoiding sticky layers by periodical check/cleaning.
7.1	Inlet air section up to after filter (Zone 21)	Hot surfaces	F	I	Periodical check of the process gas filter.
7.2		Flames and hot gases	F	I	Temperature monitoring, Periodical check of the process gas filter, Periodical check of the wire mesh of the flow inlet.

2.8 Iteration of Risk assessment procedure

After the application of all these preventive and protective measures indicated in Table 10, a new risk estimation and risk evaluation has been made with the result shown in Table 12.

Table 12. Probability (P) and Impact (I) of explosions and resulting risk levels after risk reduction measures

Ref.	Unit	Effective ignition source	Risk		After application of safety measures
			P	I	
4.1	Inside fluid bed granulator (Zone 20)	Hot surfaces	F	I	Installation of temperature monitoring systems.
4.2		Flames and hot gases	F	I	
4.4		Electrical apparatus	F	I	Only installation of certified electrical apparatus.
4.6c		Static electricity: propagating brush discharge	F	I	Avoiding sticky layers by periodical check/cleaning.
4.6e		Static electricity: spark discharge	F	I	Installation of an earthing monitoring system.
4.13		Exothermic reaction and self-ignition of dusts	F	I	Installation of temperature monitoring systems. Avoiding sticky layers by periodical check/cleaning.
5.1	Outlet air section between product retaining filter and police filter (Zone 21)	Hot surfaces	F	I	Installation of temperature monitoring systems.
5.2		Flames and hot gases	F	I	
5.6c		Static electricity: propagating brush discharge	F	I	Avoiding sticky layers by periodical check/cleaning.
5.6e		Static electricity: spark discharge	F	I	Installation of an earthing monitoring system.
5.13		Exothermic reaction and self-ignition of dusts	F	I	Installation of an earthing monitoring system. Avoiding sticky layers by periodical check/cleaning.
6.3	Outlet air section after police filter (Zone 22)	Mechanically generated sparks	F	II	Only installation of certified fan (3D).
7.4	Inlet air section up to after filter (Zone 21)	Electrical apparatus	F	I	Only installation of certified electrical apparatus.
7.6e		Static electricity: spark discharge	F	I	Installation of an earthing monitoring system.
7.13		Exothermic reaction and self-ignition of dusts	F	I	Installation of a temperatur monitoring system. Avoiding sticky layers by periodical check/cleaning.

The risk level shown in Figure 5 has been determined after the iteration process using the risk-profile grid shown in Figure 1.

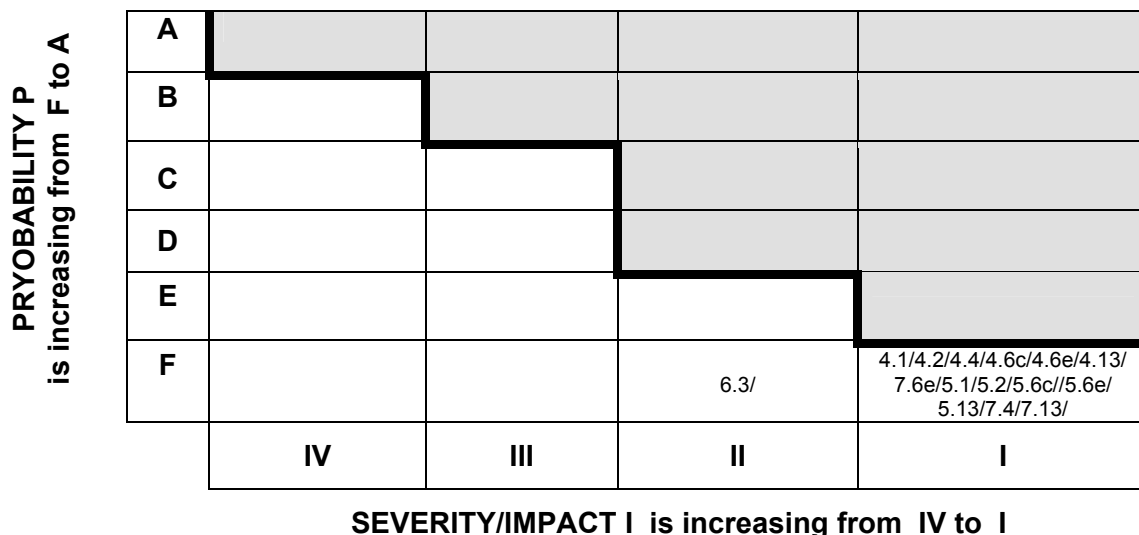


Figure 5. Risk profile for the fluid bed granulator after iteration process

All risks shown in Table 9 and Figure 5 are now below of the safety objective line (white area) using the measures indicated in Table 12. They are within the safety-target area and therefore considered to be acceptable.

2.9 List of actions as result

In the list of actions one describes concretely, how the risks above the safety-objective (stepped line) are to be decreased. In addition it is recorded who has to implement the measures and up to which time. This helps the responsible project manager when planning and facilitates the control of the measures.

Table 13 gives examples of such a list of actions.

Table 13: List of actions for the inside of the fluid bed granulator, FBG including the Risk Profile, RP before (1st RP) and after the iteration process (2nd RP)

Ref.	P / I 1 st RP 2 nd RP	Effective ignition source	Cause	Effect	Measures	Who?	Until	Status
4.1	D / I F / I	Hot Surfaces	Too hot air inlet temperature	Explosion	Installation of temperature monitoring systems.	X	Date	3
4.2	D / I F / I	Flames and hot gases	Too hot air inlet temperature	Explosion	Installation of temperature monitoring systems.	X	Date	2
4.4	C / I F / I	Electrical apparatus	Short circuit of electrical apparatus	Explosion	Installation of certified electrical apparatus.	Y	Date	1
4.6c	C / I F / I	Propagating brush discharge	Sticky layers	Explosion	Avoiding sticky layers by periodical check/cleaning.	Y	Date	1
4.6e	C / I F / I	Spark discharge	Earthing is no longer effective	Explosion	Installation of an earthing monitoring system.	Z	Date	1
4.13	D / I F / I	Exothermic reaction and self-ignition of dusts	Too hot air inlet temperature	Explosion	Installation of an temperature monitoring system and avoiding sticky layers by periodical check/cleaning	Z	Date	1
I: Impact/Severity (Categories)			P: Probability (Stages)			Status: 1 Pendent		
I : Catastrophic		III: Minor	A: Frequent C:Occasional E: Improbable			2 In process		
II : Critical		IV: Insignificant	B: Often D: Rare F: Impossible			3 Completed		

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