Acetonitrile spill in a pharmaceutical plant

06/09/2021

Aramon (Gard)

France

Manual operations
Modifications
Procedures, instructions and guidelines
Training

THE FACILITIES

The site:

This pharmaceutical plant produces active substances for medicinal products. There are about 1,000 employees who work on-site.

The site covers an area of 85 hectares and is located on the banks of the Rhône, with very few residential buildings in its vicinity. The industrial facilities occupy 20 hectares and comprise some 40 buildings. The site has a system of chemical sewers connected to a specific basin of its wastewater treatment station.

The site falls under the following two European directives:
* Seveso (upper tier) as it directly exceeds the thresholds of classified facilities for environmental protection (ICPE) categories relating to the storage and use of acutely toxic substances, products that are hazardous to the aquatic environment, or specific carcinogenic substances or mixtures;
* IED (industrial emissions) because of manufacturing activities involving chemical or biological transformation of pharmaceutical products and the disposal or recovery of hazardous waste in a co-incineration plant.

The site is subject to a technological risk prevention plan (PPRT).

The unit:

The incident took place in a production workshop producing several active substances.

This workshop operates by batch and requires many manual operations to set up the various circuits for transferring the necessary products. These circuits are assembled using various distribution panels. After the installation of a circuit, a pressure test is required to check its tightness before any production start-up.

Each production operation is guided by a document called a "Manufacturing Sheet". For each batch, it describes the architecture of the transfer circuits to be implemented by the technician and the actions to be performed. If there is a modification or deviation from this sheet, an "undescribed situation sheet" is opened to manage and trace the adjustment necessary.

The transfer operation:

Production of the active substance involved in the incident is therefore organised in successive batches. Each batch requires different transfer operations between receiving tanks and reactors, including, in particular, the transfer of recycled mother liquor.

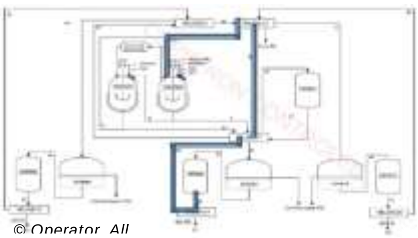


Figure 1: Transfer circuit

For this transfer, the technician had to set up a circuit connecting a receiving tank located on level 0 of the workshop to one of the two reactors located on level 6 metres.

The installation consists in connecting hoses between 3 distribution panels on level 0 (receiving tank level), level 3 m (intermediate panel) and level 6 m (reactor level).

Photo 1: Distribution panel (level 0 m)

The product used during the transfer involved in the incident consists of recycled mother liquor of a substance mainly composed of acetonitrile (CAS No. 75-05-8). Acetonitrile is a highly flammable liquid. It is also harmful due to the volatile organic compounds (VOCs) it releases.

THE ACCIDENT, ITS CHRONOLOGY, EFFECTS AND CONSEQUENCES

The accident:

On Monday 6 September 2021, at approximately 3:45 am, a product transfer operation was in progress between the receiving tank and one of the two reactors in the workshop. Only half of the volume of the product had to be transferred. When the target level was reached, the technician went to the operations room to close the bottom valve of the receiving tank and stop the transfer. When arrived in the vicinity of the room, the technician noticed a leak of liquid flowing down through the levels. Because of this flow, the technician could not access the room to close the valve. The technician then went around the area of the leak and went to the upper level (+3 m) to see whether the leak was coming from the intermediate distribution panel on that floor. The technician noticed an even more abundant leak from the upper level (+6 m). By a circuitous route, the technician reached this level and noticed a large puddle on the floor and a stream of solvent between the two reactors. The technician then immediately went into the control room and

Photo 2: Spread area (level 6 m)

triggered the emergency stop at 03:55. In accordance with procedures in force, the technician broke the break-glass emergency box, which triggered the internal emergency plan alarm, evacuation of the workshop and lockdown of the facility. The discharge valve for discharging aqueous effluent from the site to the Rhône was closed. The emergency response team set up a safety perimeter. The measurements performed confirmed a high concentration of VOCs in the workshop. Ventilation of the premises was started, and a small hose station was used to dilute the leak on the floor and allow its rapid drainage to the chemical sewer and then the toxic waste basin of the wastewater treatment station. The internal emergency plan was lifted at 05:25 am.

Photo 3: Unconnected process hose

The spill occurred through a process hose that was not connected to the transfer line and not plugged.

The consequences:

The entire receiving tank containing 2,600 L spilled. There were no injuries and no impacts outside the site (no environmental consequences, no need to implement measures to protect the public).

The site's internal units treated the effluents.

European scale of industrial accidents:

By applying the rating rules applicable to the 18 parameters of the scale officially adopted in February 1994 by the Member States' Competent Authority Committee for implementing the "SEVESO" Directive on handling hazardous substances and in light of available information, this accident can be characterised by the four following indexes:

■ □ □ □ □ □	Dangerous materials released
□ □ □ □ □ □	Human and social consequences
□ □ □ □ □ □	Environmental consequences
€ ■ □ □ □ □ □	Economic consequences

The parameters composing these indices and their rating methodology are available here.

Dangerous materials released: the amount of acetonitrile spread was 2,600 litres, or depending on the density of the product, about 2 metric tons. Because this amount represents less than 0.1% of the Seveso acetonitrile threshold (50,000 t), level 1 of the scale was decided.

Human and social consequences: no injuries were reported, and no emergency measures outside the site were necessary (confinement of residents, safety perimeter), so level 0 of the scale was decided.

Environmental consequences: there have been no environmental consequences. Therefore, level 0 of the scale was decided.

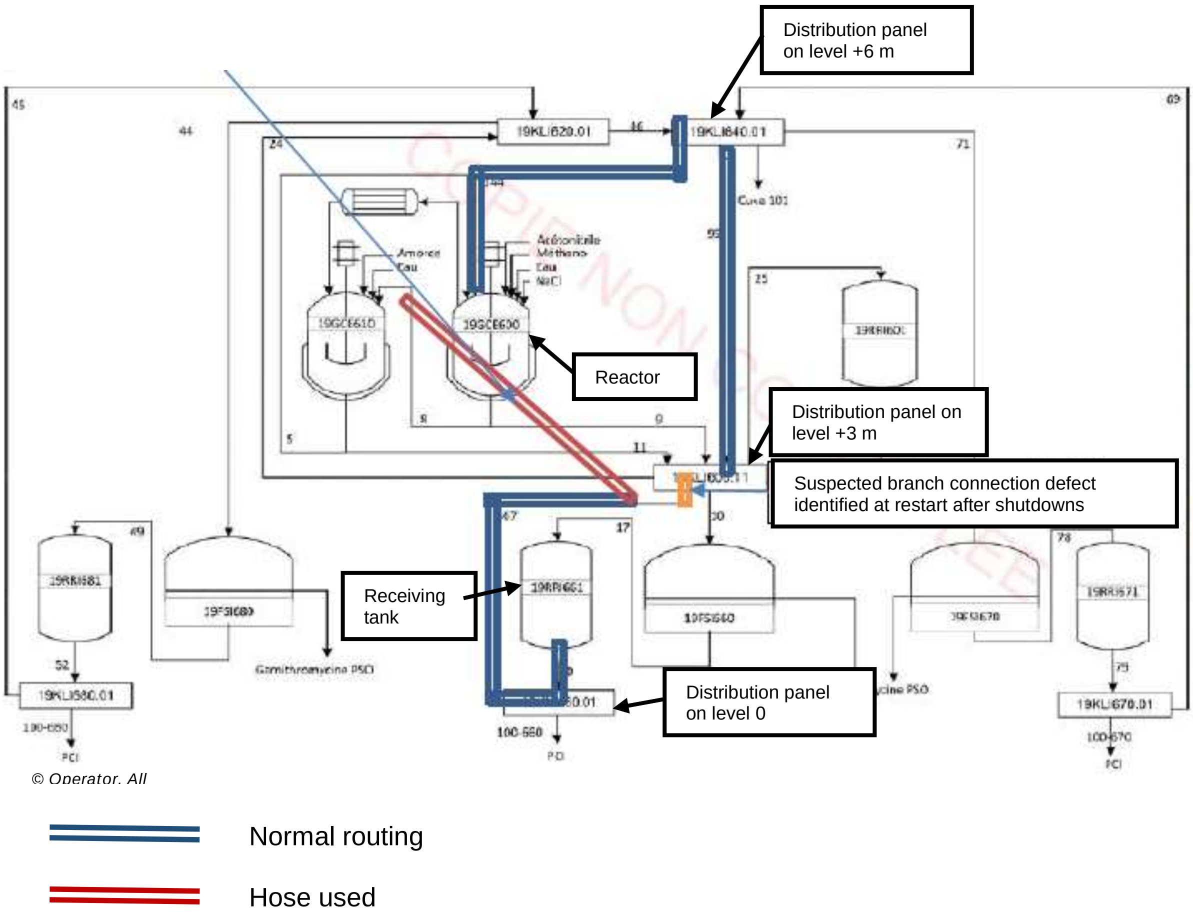
Economic consequences: The cost of cleaning and decontamination measures, estimated at €10,000 , corresponds to the lower limit of parameter 18 of the scale. Level 1 was decided. The loss of products is estimated at €50,000, an amount without impact on this classification (lower limit of parameter 16 at €100,000).

THE ORIGIN, CAUSES AND CIRCUMSTANCES SURROUNDING THE ACCIDENT

This spill was caused by a configuration defect in the transfer circuit between the receiving tank and the reactor. The technician responsible for setting up the circuit did not have the information that the reference configuration had been modified.

In this case, about 10 days before the incident, at the beginning of the morning shift, a technician had found that the branch connection of the line connecting the 0 m level distribution panel to the +3 m level distribution panel was defective. The production team called the on-call service staff who decided to stop the transfer of product that was to take place, which was non-blocking for the production of the current batch, and to request a maintenance repair action to be taken before the next production batch, scheduled for 6 days later. The repair was rated as medium priority because it did not block production, and was scheduled to take place 4 days later. In view of the scheduled rapid response time, which in this case did not require modification of the line, the workshop manager did not consider it necessary to draw up an undescribed situation sheet.

However, the following day, faced with emergencies that had be dealt with as a priority, the maintenance department postponed the repair. A circuit deviation was set up for the next transfer 5 days later. The deviation consisted in installing a hose on the fixed line located upstream of the intermediate distribution panel (level +3 m) and connecting the reactor directly, bypassing the intermediate distribution panels (level +3 m) and upstream (level +6 m). At the end of the operation, the hose was disconnected from the reactor and not plugged. On the day of the incident, another 5 days later, during a new product transfer, the information on this modification was lost.



At the same time, the technician made an alignment error. This error had no consequence on the transfer circuit reconfigured in the previous days and therefore did not constitute an aggravating factor in the situation. However, without it, the technician could have detected an unusual situation by seeing that the relevant branch connection was sealed off.

On the day of the incident, on the intermediate distribution panel (level +3 m), the inlet of the usual line, which corresponds to the branch connection found to be defective, was physically sealed. The adjacent branch connection had an identification whose numbers and letters are similar to the defective branch connection. In addition, the label was slightly damaged as a result of repeated contact with the transferred substances. This connection, which was no longer useful, was sealed on the upstream distribution panel (level 0 m) but not on the intermediate distribution panel on the level where the technician was (level +3 m). Because the technician did not have the circuit modification information, the technician automatically connected the hose to the adjacent branch connection (thinking it was being connected at the correct location). The technician therefore incorrectly thought that the resulting transfer circuit complied with the manufacturing sheet.

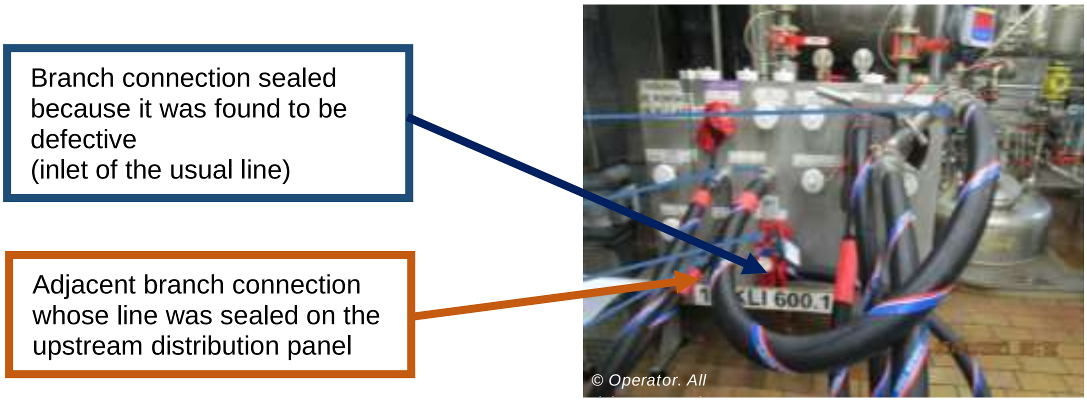
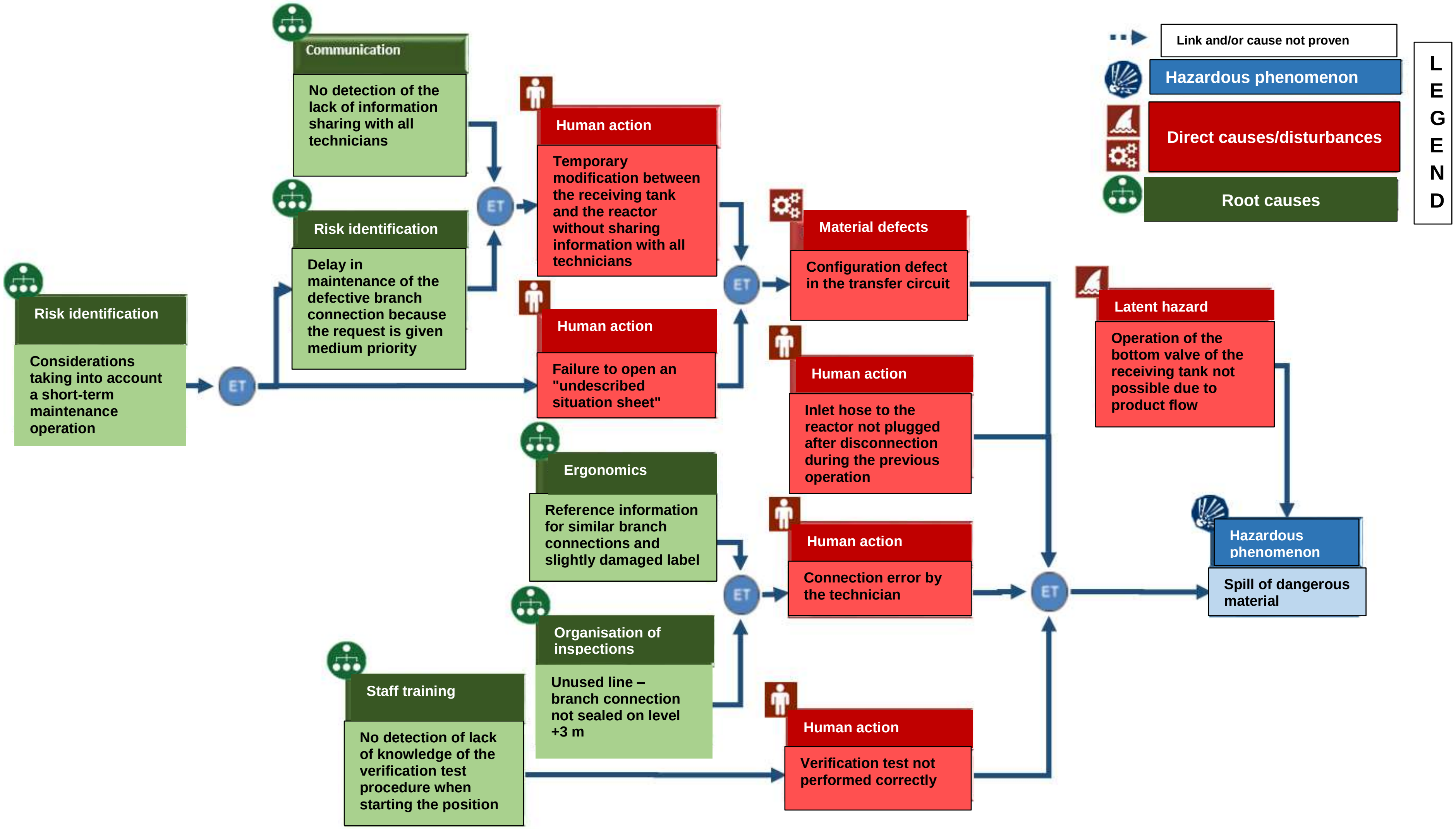


Photo 4: Distribution panel, level +3 m

Finally, at the end of the installation of the circuit, the technician performed a pressure test to check tightness before any product transfer. However, this test did not comply with the standards recommended for this workshop and did not make it possible to detect leaks in the line. The technician analysed the results and found that the installation was compliant although it was not. Similarly, without this error, the technician could have detected the unusual configuration.

The technician had been working in this workshop for about one year. The technician previously worked in another workshop on the site where this type of test is mainly performed automatically and seldom manually. The technician was trained by coaching in this new workshop, without formal assessment of the ability to perform pressure tests. This lack of knowledge of the "pressure test" procedure was not known when starting the new position.


Communication
No detection of the lack of information sharing with all technicians
Risk identification
Delay in maintenance of the defective branch connection because the request is given medium priority
Risk identification
Considerations taking into account a short-term maintenance operation
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Human action
Temporary modification between the receiving tank and the reactor without sharing information with all technicians
Human action
Failure to open an "undescribed situation sheet"
Ergonomics
Reference information for similar branch connections and slightly damaged label
Organisation of inspections
Unused line – branch connection not sealed on level +3 m
Staff training
No detection of lack of knowledge of the verification test procedure when starting the position
Material defects
Configuration defect in the transfer circuit
Human action
Inlet hose to the reactor not plugged after disconnection during the previous operation
Human action
Connection error by the technician
Human action
Verification test not performed correctly
Latent hazard
Operation of the bottom valve of the receiving tank not possible due to product flow
Hazardous phenomenon
Spill of dangerous material
Link and/or cause not proven
Hazardous phenomenon
Direct causes/disturbances
Root causes
LEGEND

ACTIONS TAKEN

After the incident, the operator took a number of actions, under different time frames.

In the short term, as immediate corrective actions to return to a normal situation and respond to the first causes identified:

- sharing of information on the temporary assembly in place with the teams and making a room posting;
- sealing off of the branch connection of the line no longer used on the intermediate distribution panel (level +3 m);
- update of the branch connection identification labels;
- new awareness raising in technicians regarding pressure tests;
- reminder to the teams and performance of a field observation visit concerning the current placement of the plugs on the lines.

In the medium term, actions to respond more thoroughly to the incident:

- sharing of incident feedback through a general reminder on the key role of pressure tests in safety;
- development and implementation of a digital training module dedicated to pressure tests for all technicians in the site's workshops through the site's training management and traceability system;
- verification that there are no unnecessary branch connections in the workshop.

LESSONS LEARNT

This incident gave rise to few consequences. These remained confined to the site and related only to the cleaning of the facilities and the treatment of the product. This limited effect was thanks to the good response of the technicians, who are aware of and regularly trained in crisis management.

However, this incident could have been avoided. Its analysis is extremely instructive and shows certain points that must not be overlooked.

First, this incident highlights the importance of the traceability of temporary modifications in production workshops and the associated communication, especially when there are a significant number of human actions taking place. The requirements established by the operator in this area in terms of communication and procedures to be followed must be very clear and easily applicable to prevent any ambiguity regarding the need for their application and to systematise their use. At the same time, the operator must ensure the complete implementation of the material modifications decided with regard to ongoing changes in the industrial tool, particularly when equipment is sealed off.

In addition, optimisation work, from the point of view of ergonomics and automation of the work environment, must make it possible to prevent situations that are conducive to an incident occurring, especially for activities requiring numerous human actions. Human errors are inevitable, and industrial activity risk assessment and crisis management serve to mitigate them and limit their consequences. However, reducing error factors at the source helps to prevent the recurrence of an incident.

Finally, the verification of the appropriateness of a technician's skills for their tasks is a key point. While the importance of the initial training of a new technician in an industry is often well noted, ongoing training throughout professional development from one position to another must not be neglected. This example shows that a proven training course may be unsuitable for revealing a lack of knowledge of a specific and key point in an experienced technician who changed positions.

In conclusion, this incident shows the importance of analysing human errors to decipher their root causes, which are generally organisational.