IUPAC COCI SAFETY TRAINING PROGRAM REPORT

(June - July 2019)

BAYER AG, BERGKAMEN, GERMANY

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Contents

Table of Figures 3
Acronyms 3
Acknowledgement 4
Executive Summary 5
1.0 Introduction 6
1.1 Bayer AG 6
1.2 Bayer AG Supply Centre Bergkamen 6
1.3 IUPAC COCI Safety Training Program 9
1.3.1 Training Program Agenda 10
1.4 Discussions and Lessons Learned 11
2.0 List of Persons Met at SCB 15
3.0 Sites Visited at the Host Company 16
3.1 Health, Safety and Environment 16
3.2 HAZOP 17
3.3 Inventory Management System 17
3.4 Production Unit A 17
3.5 Production Unit B 18
3.6 Production Unit E 18
3.7 Microbiology Plant 19
3.8 Production Unit F 19
3.9 Ground Water 19
3.10 Incineration and Disposal Plant 19
3.11 Power Plant 20
3.12 Distillation Plant and Solvent Recovery 20
3.13 Waste Disposal, Incinerator and Recovery of Sodium Iodide 20
3.14 Bayer AG Training Centre 21
3.15 Facility Management, Site Security, Cyber Security and Emergency Response 21
3.16 The Safety Training 21
3.17 Safety Culture 22
3.19 Audits 23
3.20 Controlling Exothermic Runaway Reactions 23
4.0 After Action Plan from the Lessons Learnt 24
4.1 At the Technical University of Kenya 24

4.2 At the Kenya Chemical Society 25
4.3 Nationally (Kenya) 25
5.0 What Went Well or Not during the Training at Host Company 25
6.0 Suggestions on How to Improve the STP Program 26
7.0 References.....26

TABLE OF FIGURES

Figure 1. Supply Center Bergkamen showing Lankcess (red) and Hunstman (yellow) (Courtesy of in der Weide)..... 7
Figure 2. Hormones (contraception / hormone replacement therapy / dermatology) produced using intermediates produced at SCB (Courtesy of in der Weide)..... 7
Figure 3. Contrast Media produced using intermediates from SCB (Courtesy of in der Weide).. 8
Figure 4. Schematic Representation of Production Units at SCB (Courtesy of in der Weide)..... 8
Figure 5. Heath, Safety and Environment rules and instruments at SCB (Courtesy of in der Weide) 16
Figure 6. Safety signage in production facilities.....22
Figure 7. Safety levels: Behavior Based Safety as a continuous improvement.....22
Figure 8. Structured implementation of the Behavioral Safety Program 23
Figure 9. Schematic diagram of a reactor with safety features to control exothermic runaway reactions 24

ACRONYMS

API - Active Pharmaceutical Ingredient
BAYSIS – Bayer Site Information Systems
cGMP - current Good Manufacturing Practise
COCI – Committee on Chemistry and Industry
CRDF - Civilian Research and Development Foundation
DFID - Department for International Development
ERP - Enterprise Resource Planning
FDA - US Federal Drug Administration
GMP - Good Manufacturing Practise
HAZOP - Hazard and Operability Study
ICCA - International Council of Chemical Associations
IFS – International Foundation of Science
IUPAC – International Union of Pure and Applied Chemistry
KCS - Kenya Chemical Society
LTRIR - Lost time reportable incident rate
OPCW - Organization for the Prohibition of Chemical Weapons
PPE – Personal protective equipment
PUF - Production Unit F
QA – Quality Assurance
QC – Quality Control
REACH - Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals

SAP – Systems Applications and Products
SCB - Supply Chain Bergkamen
STP – Safety Training Program

ACKNOWLEDGEMENT

I thank the brilliant minds at IUPAC COCI committee and their COCI Safety Training Program subcommittee who initiated the programme over 20 years ago and who continue to help STP Fellowship trainees from the developing nations to learn about the operations, safety, security and environmental protection in modern chemical industries.

I acknowledge the extensive efforts by Dr. Laura McConnel (Bayer Crop Sciences, USA) for all her hard work in initiating this training and facilitating/coordinating with Thomas in der Wider over the past 2 years that made this training possible. Special thanks go to Thomas in der Wider, who coordinated my training at Bayer SC Bergkamen and kept my weekends busy by organising weekend trips and visits to historical sites in the City of Dortmund. Many thanks to the HSE team (Sonja, Michael), who made my stay at SC Bergkamen comfortable and pleasurable.

My appreciation to Bernd Renzing, Stefan Klussmann, Maik Rock, Andreas Rielage (PUA), Martin Krappe, Harald Peter (PUB), Stefan Koep, Sven Albring (PUE), Jens Pilling (Microbiology Plant), Georg Kivitz (IU), Stefan Veit (HSE), Stefan Diehle, Franziska Krauf, Marc Zibulski (PUF), Dieter Wehmeier, Klaus Vissmann, Klaus Umann (IU), Dennis Panknin (DF), and Sefan Wahl (SMRP) for teaching me about the various operations at SC Bergkamen.

Last but not least, I acknowledge the support from CRDF who organised and funded my travel to and from Kamen, Germany and to Paris, France to the 2019 IUPAC Conference. And COCI STP for inviting me to the 2019 STP Workshop where I presented some of the knowledge gained from SC Bergkamen.

EXECUTIVE SUMMARY

Supply Center Bergkamen, Germany hosted Austin Ochieng Aluoch from Kenya for the International Union of Pure and Applied Chemistry's (IUPAC) Committee on Chemistry and Industry (COCI) Safety Training Program (STP) Fellowship training. The STP Fellowship training took place in June-July 2019 and was jointly supported by IUPAC COCI, CRDF and Bayer AG.

The COCI STP Fellowship training program provided an opportunity to learn about chemical safety, chemical security, environmental protection and related topics through a four-week training at the Bayer SC Bergkamen site. During this period, Austin worked, shadowed or held discussions with professionals in the Health Safety and Environment (HSE) department, Production Plants, Bayer Training Centre, Wastewater Treatment Plant, Facility Management, Incineration and Disposal Plant, Power Plant and Site Security. He gained knowledge in modern safety and security practices, industrial standards, environmental protection, solvent recycling and recovery and modern waste management practices. The STP Fellowship training covered aspects of a closed system and its advantage in environment protection and reporting requirements, cGMP and the standards/audits requirements for an API manufacturing industry. The training covered HAZOP analysis of a boiler that had been used for 5 years and was due for replacement. Cybersecurity to protect the process control, office operations, access control and ERP from cybercrime, formed an important aspect of the training. At SCB all the production processes are automated and controlled in each plant from a central process control room.

The SAP ERP is used to monitor products such as testosterone, which are prone to theft and are flagged on the SAP system as a theft risk. Other dual use chemicals such as thionyl chloride, acetone cyanohydrin (audited by Evonik), DMSO, hydrogen fluoride and methyl ethyl ketone are also monitored but not flagged as in a similar way to testosterone.

Bayer AG, Bergkamen produces around 30000 tonnes of waste annually, 12500 tonnes of the liquid waste and 1500 tonnes of the solid waste in incinerated in rotary kiln incinerator (department disposal facilities, DF) and is dedicated to protecting the environment. In this regard, SCB recycles solvents used in production (department solvent management and recovery plant, SMRP). The recycling of waste solvents (about 60%) saves money and the environment. The rest of the solvents, the azeotropic mixtures, are used to generate steam which is used to sterilize the microbiology plant. The steam is also used to generate electricity. SCB has its own power supply which can support the plant in case there is no power from the town grid (the power plant is part of the department "infrastructure Utilities" (IU)). Membranes are used to remove biological materials and activated carbon to remove non-biological materials from the solvents. Sodium iodide is used in PUF for the production of contrast media. The iodine in the iodine containing waste is recovered by an incineration process in the DF and is reused in other industrial processes. The sodium iodide (17%) is not used in production because it is not pharmaceutical grade, it is sold to other companies, therefore generating income from its waste.

Membranes are used to remove biological materials and activated carbon to remove non-biological materials from the solvents. Solids from production and sludge from the wastewater treatment plants are incinerated. The ashes produced after the incineration have been determined

to be inert (through analysis). The inert ashes are dumped into landfills (only for ashes with less than 3% total organic content), used to make tarmac roads or used to fill salt mines.

Upon return to Kenya the IUPAC COCI STP Fellowship trainee (Austin) plans to disseminate the lessons learnt at Bayer SCB by giving seminars and presentations at various forums at the Technical University of Kenya and the Kenya Chemical Society. He also plans to incorporate aspects of process control into the Bachelor of Technology in Industrial Chemistry Curricula at the School of Chemistry and Material Science, technical University of Kenya.

1.0 INTRODUCTION

1.1 BAYER AG

Bayer is a Life Science company with a more than 150 year history and core competencies in the areas of health care and agriculture. With its own innovative products, Bayer contributed to finding solutions to some of the major challenges of our time. Bayer's goal is to create value for customers, stockholders and employees, while also strengthening the earning power, operating sustainably and addressing social and ethical responsibilities (Bayer, 2019).

The Bayer Group is managed as a Life Science company with three divisions – Pharmaceuticals, Consumer Health and Crop Science – and the Animal Health business unit. In 2018, the Bayer Group comprised 420 consolidated companies in 90 countries throughout the world. The Global headquarters are in Leverkusen, Germany. The "Pharmaceuticals" division focuses on prescription products, especially for cardiology and women's healthcare, and on specialty therapeutics in the areas of oncology, hematology and ophthalmology. The division also comprises the radiology business, which markets diagnostic imaging equipment together with the necessary contrast agents. The "Consumer Health" division markets mainly nonprescription (OTC = over the counter) products in the dermatology, nutritional supplement, analgesic, digestive health, cold, allergy, sinus and flu categories. The "Crop Science" division is a world-leading agriculture enterprise with businesses in seeds, crop protection and nonagricultural pest control. The "Animal Health" business unit ranks among the leading international innovators in its field. It develops and markets products and solutions for the prevention and treatment of diseases in companion and farm animals (Bayer, 2019).

In December 2018, Bayer had a total 116,998 employees worldwide, with 55,371 in Europe/Middle East/Africa, 15,145 in Latin America, 23,872 in Asia and 22,610 in North America (Bayer, 2019).

1.2 BAYER AG SUPPLY CENTRE BERGKAMEN

Bayer AG Supply Chain Bergkamen is located in the City of Bergkamen which is about 26 kilometres from the centre of Dortmund, the home of the famous football team Borussia Dortmund. Bayer AG acquired the Supply Centre Bergkamen site in 2006 to produce pharmaceuticals and chemicals. Currently, Bayer shares the site with two other companies, Hunstman and Lankcess. Figure 1 shows the aerial view of SC Bergkamen site with the red and yellow boarders showing Huntsman and Lankcess sites respectively.

Figure 1. Supply Center Bergkamen showing Lankcess (red) and Hunstman (yellow) (Courtesy of in der Weide)

The Supply Center Bergkamen (SCB) is a multi purpose plant which produces APIs. A total of 49 APIs (30 Steroid hormones, 11 Corti-coides, 8 Therapeutics and contrast media) some involving nearly 200 synthesis steps are produced. SCB is the largest API production plant at Bayer. Some of the chemical synthesis steps have been replaced by microbiological steps. The microbiological fermentations, which use yeast, fungi, or bacteria replace 4 or more chemical synthesis steps. Due to the numerous synthesis steps, some APIs are produced only once every three years, which requires precise planning and excecution. The SCB plant also produces 80 tonnes of hormones (Figure 2), over 1400 tonnes of contrast media (Figure 3), about and over 9000 tonnes of intermediates.

The production at SCB is highly automated. Each plant has a central process control room. The design of all the production is such gravity is used is to aid the flow process. Loading of raw materials and mixing of reactants is done on the highest floor. The next floor reactions and preciptation are performed. Separation is done on the next floor using centrifuges (sometimes Nutsche filters or combined as Nutsche filterdryers) are used. On the ground floor contains paddle dryers (and types of other dryers) and product filling stations. Some reactions involved in the production processes include bromination, fluorination, Grignard reactions, Simmons-Smith, Oxidation as Oppenauer and reductions with hydrogen, lithium (Birch) and catalysis using nickel.

Figure 2. Hormones (contraception / hormone replacement therapy / dermatology) produced using intermediates produced at SCB (Courtesy of in der Weide)

There are several other facilities which support the production plants to take care of the waste, exhaust gases, process and wastewater, high volumes of solvent (which must be pharmaceutical quality, therefore requiring distillation). In this regard, SCB site also has a Wastewater treatment plant (that uses membrane technology), Power Plant for steam and electricity supply, Site Security, Fire Brigade, Waste Incinerator, Tank farms, distillation plant, process water treatment plant, Process control rooms and Process IT (to prevent cyber-attacks).

Figure 3. Contrast Media produced using intermediates from SCB (Courtesy of in der Weide)

Bayer AG's mission is "Science for a better life", this includes corporate social responsibility, for example sharing the organizations knowledge especially in occupational safety, environmental aspects, plant and process safety and security. Consequently, SCB accepted to work with the COCI STP Coordinator for their STP Fellowship training program to train Austin Ochieng Aluoch, who is a university lecturer from the Technical University of Kenya and a member of the National Governing Council of the Kenya Chemical Society (KCS).

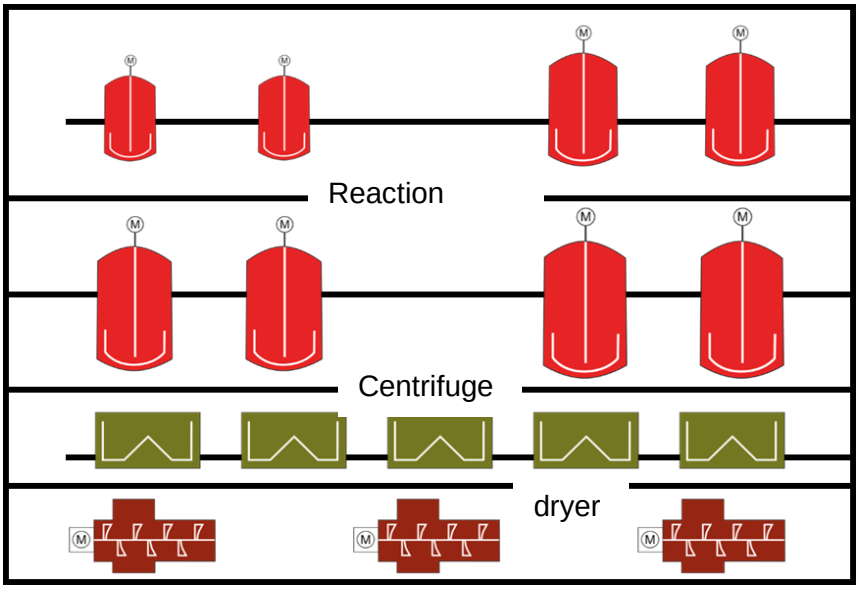

Figure 4. Schematic Representation of Production Units at SCB (Courtesy of in der Weide)

1.3 IUPAC COCI SAFETY TRAINING PROGRAM

The International Union of Pure and Applied Chemistry (IUPAC) is the worldwide authority on chemical nomenclature and terminology, including the naming of new elements in the periodic table, standardized methods of measurement and on atomic weights and other critically evaluated data (IUPAC, 2019). IUPAC is a global leader in the provision of objective scientific expertise for the resolution of critical global issues that involve chemistry, and of which have societal impact. IUPAC is therefore involved in a wide range of diverse activities that ultimately impact both the chemistry profession and society. A long-term key goal of IUPAC has been to build chemistry-based capacity and change attitudes to help improve both safety and security in developing countries. The IUPAC COCI Safety Training Program (STP) is one such program that is undertaken by the Committee on Chemistry and Industry (COCI).

The COCI STP supports STP Fellowship trainees from developing countries to visit plants of IUPAC Company Associates [the Host] in the industrialized world where they learn about safety, security and environmental protection. Safety Training Program Fellowship trainees are mid-career chemists and chemical engineers in a supervisory or managerial level in chemical companies, government institutions or scientific institutions engaged in aspects of safety, security and environmental protection in chemical, pharmaceutical, or biotechnological production or in the teaching of these fields. The applicant and their nominator certify that the applicant has the ability and authority, as a trainer, to provide leadership and influence safety and security practices in their home territory, not only in their specific workplace, but also more broadly throughout academic institutions, chemical industries, governments, and the public as a result of this safety training. Once accepted as being eligible for the STP Fellowship training program, the STP Coordinator arranges and coordinates the training at an IUPAC Company Associate company [the Host] in an industrialized country. The training is organized at a mutually agreeable time, for two to three weeks involving on-site safety, environmental protection and security training at a Chemical, Pharmaceutical or Biotechnical Research and Production company with expertise in safety, environmental protection and security practices. Accommodation, subsistence and travel expenses are provided for all STP Fellowship trainees.

Since 2000, 19 STP Fellows from Kenya, Turkey, Egypt, Nigeria, China, India, Ghana and Uruguay have received STP Fellowship training at 13 Host Companies in the United States of America, Canada, South Africa, United Kingdom, Denmark and Belgium. The STP Fellowship trainees are required to submit a detailed training report to the STP Coordinator within two months of the Host Company training. Once the trainee's draft report is received and their final report is approved by the STP Coordinator and the COCI Chair, the trainee will be designated a COCI *"STP Fellow"*. They receive an *"STP Fellows Certificate"* confirming the successful completion of their training. The STP Coordinator then shares that final report with the Host Company and any additional funding agency. Subsequently, a second report must be received by the STP Coordinator 1 year after the candidate returns home, detailing concrete actions archived, plans for the near future (within 2-3 years) and ongoing plans for the longer term. Or, the STP Fellows may be invited to participate in biennial COCI Safety Training Program Workshops at IUPAC General Assembly/Congresses. The STP Fellow presents their training experience and how they have, as a trainer, provided concrete leadership and influence in the safety and security practices of their place of employment, the Chemical Industry and more broadly in their home country as a

result of this safety training. Their presentation shall include an outline of plans for the near future (within 2-3 years) and ongoing plans for the longer term. They also share experiences, best practices and plans with each other and participate in continuing efforts to enhance the STP Fellowship Program.

The 2019 STP Fellowship training program hosted Austin Ochieng Aluoch at the Bayer AG SC Bergkamen site. This training was coordinated by Thomas in der Weide who heads the HSE department at SCB. The STP Fellowship trainee familiarized himself with HSE activities, visited and spoke to personnel from the following facilities; HSE, PUA, PUB, PUE, Microbiology Plant, Bayer Training Centre, PUF, Wastewater Treatment Plant, Facility Management, Incineration and Disposal Plant, Power Plant, Site Security. Table 1 shows the training Agenda and the activities, a list of Bayer AG SCB personnel visited and their location.

1.3.1 Training Program Agenda

Table 1. COCI Safety Training Program Agenda

Date	Session	Activity	Instructor
Tuesday, 18-06-2019		Arrival and Hotel Check-In	Thomas in der Weide
Wednesday, 19-06-2019	0830 -1600	Site Overview RC at Bayer; HSE Key Principles: Audit-Schemes overview: OHSAS 18001, EMAS, ISO 14001, environmental management, exhaust gas treatment, substance detection in case of an emergency, chemical weapons; documentation of the production process according chemical weapons New employees` safety training	Thomas in der Weider Hans-Ulrich Weiler
Thursday, 20-06-2019	Holiday "Fronleichnam"		
Friday, 21-06-2019	0830 - 1600	Key performance indicators occupational safety, job safety analysis at Bayer, occupational safety programs (behavior based safety), last minute risk assessment, compliance management	Thomas in der Weide Sonja Hess
Monday, 24-06-2019	0830 - 1600	IT-security, especially security of process control systems	Bernd Renzing
Tuesday, 25-06-2019	0830 - 1000	Production overview	Maik Röck,
	1000 - 1600	Production Unit A: safety concepts; Hydrogenation; Ethynylation; industrial hygiene for components with very low OEL	Ingo Ortman; Andreas Rielage
Wednesday, 26-06-2019	9.30 - 1600	Zuerst Production Unit B, danach Production Unit E: safety concepts for handling self igniting substances; bromine, HCN, exothermic and gas evolving reactions as Simmons-Smitth, Grignard etc.	Martin Krappe; Stephan Koep
Thursday, 27-06-2019	0830 - 1030	weighing and booking of dangerous substances - SAP-System	Andreas Hauschulte

	1030 - 1600	Microbiological Plant: safety concepts; bacteria and genetics, laboratories; Job safety analysis	Frank Berendes; Jens Pilling
Friday, 28-06-2019	0830 - 1600	Groundwater protection, Soil-Management Waste management - especially dangerous waste	Stephan Veit; Georg Kivitz Thorsten Kopf
Monday, 01-07-2019	0900 - 1600	Production Unit F, safety concepts; Thionyl chloride; Dichloroethane; Hydrogenation	Stefan Diehle
Tuesday, 02-07-2019	0830 - 1600	Plant and Process safety; safety concepts; runaway reactions; Hazard and Operability Studies (HAZOP); HSE regulation framework	Thomas in der Weide
Wednesday, 03-07-2019	0830 - 1030	Security process from visitor to employee	Klaus Vissmann
	1030 - 1230	Emergency Response Team and crisis center Wastewater treatment	Helmut Bennemann, Sophie Krejcik
	1400 - 1600	Pharmaceuticals in the environment, endocrine disrupters,	Thomas in der Weide
Thursday, 04-07-2019	0830 - 1600	Power plant with safety concepts against high pressure steam; incineration, Fire Brigade; security control; central control room	Klaus Urmann, Martin Neumann
Friday, 05-07-2019	0830 - 1000	Wrap Up	Thomas in der Weide
	1000 - 1200	Distillation plant, Process water treatment, safe and secure storage of liquids	Steffen Wahl
	1400 - 1600	Waste incineration, safety concepts; process control system concerning incinerators, safe and secure handling of waste; environmental aspects of waste incineration	Helmut Bennemann
Monday, 08-07-2019	0830 - 1600	IUPAC Conference 2019 STP Workshop in Paris, France	
Tuesday, 09-07-2019	0830 - 1600	Travel from Paris, France	
Wednesday, 10-07-2019	0830 - 1600	security, safety and environmental aspects for trainees	Karl-Heinz Grafenschäfer
Thursday, 11-07-2019	0830 - 1200	Wrap -up	Thomas in der Weide

1.4 Discussions and Lessons Learned

In this section, a list of the lessons learnt are discussed:

1. SCB being a multipurpose plant that produces several APIs, that include several synthesis steps, meticulous planning and widespread automation of production is employed. This achieved through regular team planning meetings and training.
2. The design of all the production is such that gravity is used to aid the flow process thereby saving costs that would otherwise be incurred to pump material. Loading of raw materials and

mixing of reactants is done on the highest floor. On the next floor reactions and preciptations are performed. Separation is done on the next floor using centrifuges. The ground floor contains paddle dryers (and types of other dryers) and product filling stations.

3. All personnel and visitors in the production areas are provided with hard hats, googles, gloves, lab coats and safety shoes as minimum PPE.
4. All the production plants are considered chemical facilities. The following reminders and signs were posted all over the production area:
   - Switch off electric devices, which are not explosion proven! Do not touch pipes or vents!
   - Wear a helmet and safety glasses!
   - Do not use your cell phone!
   - Keep a distance from the walls inside the elevator!
   - Do not smoke!
   - Use handrails!

Figure 5. Safety signage in production facilities

5. SCB has put in a lot of resources and time to instil a safety culture among all personnel. Senior management receives regular training to lead the safety culture at SCB.
6. Employees at all levels are equally comfortable stopping each other when at-risk behaviour is observed and recognizing each other when safe behaviour is observed.
7. No one is blamed for near misses or incidents; instead systemic causes are identified, and changes are made to prevent those near misses and incidents from happening again. The fear of discipline which drives under-reporting and reduces involvement has been driven out.
8. With the wide range of chemicals and several infrastructure plants, Health, Safety and Environment (HSE) is an important aspect of SCB. In this regard, SCB has a dedicated HSE department with several experts, who conduct internal audits and coordinate external audits.
9. SCB participates in audits for HSE management systems EMAS (European), ISO14001 (environment), OHSAS 18001 (occupational safety and health), ISO 50001 (energy) standard. Figure 5 summarizes some of the rules, standards and instruments that HSE maintains at SCB.
10. All manufacturing is done under cGMP. Several internal and about 15 external audits are conducted annually by various stakeholders including German authorities, US Federal Drug Administration (FDA), Japanese authorities, Korean authorities, Russian authorities, Evonik and OPCW.
11. Other audits include those on energy management, AMAS audit for environmental management, IED (Industrial Emissions Directive) EU audit and TuV audit (safety of equipment).
12. Bayer AG is a member of the Responsible Care® initiative by ICCA. Responsible Care® is a voluntary commitment by the global chemical industry to drive continuous improvement and achieve excellence in environmental, health and safety and security performance. Evonik, audits Bayer AG for its use of acetone cyanohydrin.

13. BIMKA is the first occupational health and safety Program implemented at SCB, which looks at Lost time Reportable Incident Rate (LTRIR). With the launch of BIMKA Unfallfrei (no incidents) the LTRIR reported annually dropped to less than 20. Since then and with the HSE department lauching behaviour based safety, the LTRIR is now less than one per year.
14. BAYSIS is used to report incidences, injuries, process safety incidences, fire, explosions, strikes, complaints from the community and natural disasters. Transportation incidences have to be reported if the transport was paid for by Bayer.
15. HAZOP is done on technical devices, equipment, reactions and processes. It is done before a new equipment is ordered and is repeated every 5 years or when the equipment is replaced.
16. SAP is the ERP system used at Bayer. It has two modules (1) Inventory management and (2) Warehousing. QA sets additional requirements which are input into SAP system, such as reporting and audit requirements. Material is tracked per drum of raw material or product and this ensures chemical safety and security of materials.
17. The SAP system is access controlled; only 4 people can make changes to it. Theft risk materials such as testosterone are flagged by the system and automated emails sent to the shipper and the recipient as a security/safety precaution.
18. Testosterone, thionyl chloride, acetone cyanohydrin (audited by Evonik), DMSO, hydrogen fluoride and methyl ethyl ketone which are dual use are monitored from the moment they get to SCB all the way to their disposal or consumption. Their production documentation are stored for 30 years.
19. GMP and HSE training for SCB personnel is conducted four times a year.
20. To protect the environment, whenever bromine is used in the production process, brushes are used to stop it from getting to the environment. It is then collected and incinerated.
21. Clean rooms, with negative pressure are used to load raw materials and collect finished products. The operators who load or collect raw materials wear put on special PPE.
22. PUB utilizes a completely closed system, which eliminates the need to register all the intermediates in the process. This saves a lot of time and costs. A completely closed system does not require the operators to have special PPE when loading raw materials or collecting the finished product. Change management had to be implemented for the operators to accept the closed system, which is a much slower process compared to the alternative.
23. Microbiological fermentations are used to replace some chemical synthesis steps, thereby increasing production efficiency.
24. Thionyl chloride which is toxic and reactive with other substances is used in PUF. In this regard, no QC sample is taken for the $SOCl_2$ when it is delivered; pre-audit of the supplier ensures quality in the supply chain.
25. Hydrogen being an explosive hazard is also handled in a special way since it causes an explosive atmosphere, therefore, all installations in the plant are explosion proof. For this reason, regular cell phones are barred from the plant. Rapture disks and safety valves are used to enhance safety.
26. The integrity of ground water around the plant is highly safeguarded and monitored. European law requires that ground water analysis is performed before a chemical company is established and every 5 years thereafter. SC Bergkamen has 50 points where ground water can be sampled for analysis. However, groundwater is not used for production.
27. To reduce consumption of municipal water, rainwater is harvested and used for non-pharmaceutical processes such as cleaning.

28. In case of spillage from the production, the fire brigade must contain the spill. In such a case the affected soil is dug out and taken to a special area where it is temporarily stored and analyzed. If it is found to be contaminated, it is taken to a landfill or incinerated.
29. Since Bayer AG is dedicated to protecting the environment 60% of all the solvents used in production are recycled. Membranes are used to remove biological materials and activated carbon to remove non-biological materials before recycling.
30. Solvents that cannot be recovered (the azeotropic mixtures) are used as fuel to produce steam. This saves energy as well as costs.
31. Solids from production and sludge from the wastewater treatment plants are incinerated and produce ashes. These ashes having been determined to be inert (through analysis) are dumped in landfills or used in road construction.
32. Neutralization is used to precipitate heavy metals. Membranes are used to remove biological materials and activated charcoal to remove non-biologicals. Polymers and $FeCl_2$ are added to speed up the sedimentation process.
33. Sodium iodide is recovered as a solid waste and is reused in PUF during the production of contrast media. The Sodium iodide is not used in production because it is not pharmaceutical grade, it is sold to other companies. Waste incineration produces 17% sodium iodide.
34. All other waste is incinerated in a rotating kiln which burns at 900 degrees Celsius and above. German authorities have online access to remotely monitor, 24 hours seven days a week, the gases released to the environment after the incineration. To control/minimize the formation of dioxides which form at 200 – 300°C, the kiln is cooled rapidly to 80°C.
35. Bayer SCB and other chemical companies in Germany have training centres, usually located within the plant. The 3-year apprentice Program focuses on practical knowledge. The students graduate as Chemical Technicians (Not a Chemical Engineer) after sitting for a National Exam offered by the German authorities and area employed by Bayer or other companies.
36. Bayer AG, Bergkamen employs a layered security approach with regular patrols inside and outside the perimeter fence. CCTV is also used to monitor the whole plant. A drone detection system in also in place.
37. A public address system connected to all buildings and production units is used to convey emergency messages. Emergency messages can also be sent to all employees via the intranet.
38. Bayer AG has a dedicated crisis center with a pre-assigned crisis team. The crisis center has phones, computers, meeting rooms, televisions and other equipment dedicated to crisis management. The crisis team trains every two weeks and their roles mimic those of the local government authorities for ease of communication.
39. Bayer AG maintains a full time IT team. Its process systems are on a different platform from the world wide web to minimize the possibility of compromise from a hacker. Furthermore, several backups on MS Windows® and UNIX® are also maintained.
40. Employees receive regular training on internet security, phishing emails and other cybersecurity matters. KeyPass is used for password management and YubiKeys to protect access to phones and computers.
41. To control runaway reactions, all reactors are built using stainless steel or enamel lined and all reactors are standardized to control runaway exothermic reactions.

2.0 List of Persons Met at SCB

Table 2. List of personnel I met at SCB

	Name	Department			Name	Department
1	Thomas in der Weide	Health Safety and Environment Department		22	Jens Pauling	Microbiology Plant
2	Hans-Ulrich Weller	Health Safety and Environment Department		23	Steffen Wahl	Distillation Plant
3	Sonja Hess	Health Safety and Environment Department		24	Waste inciniration	Helmut Bennemann
4	Bernd Renzing	IT Department		25	Karl-Heinz Grafenschafer	Training Centre
5	Maik Rock	Production Unit A		26	Georg Kivitz	Groundwater
6	Ingo Ortman	Production Unit A		27	Stefan Veit	Groundwater
7	Andreas Rielage	Production Unit A		28	Franziska Knauf	Production Unit F
8	Martin Krappe	Production Unit E		29	Dieter Wehmeier	HAZOP
9	Stephan Koep	Production Unit B		30	Mark Zibulski	Production Unit F
10	Andreas Haushulte	Warehouse		31	Denis Panknin	Incineration Plant
11	Stefan Klussmann	Site Security		32	Calix Kenmognie	IT Department
12	Andreas Feih	Facility Management				
13	Frank Berendes	Microbiology Plant				
14	Stefan Diehle	Production Unit F				
15	Harald Peter	Production Unit B				
16	Sven Albring	Production unit E				
17	Klaus Vissmann	Site Security				
18	Helmut Bennemann	Emergency Response				
19	Sophie Krejcik	Wastewater Treatment Plant				
20	Klaus Umman	Power Plant				
21	Martin Neumann	Fire Brigade, Control room				

3.0 Sites Visited at the Host Company

In the following sections, the lessons learnt during the visits to the various facilities is summarised.

3.1 Health, Safety and Environment

With the wide range of chemicals and several infrastructure plants Health, Safety and Environment (HSE) is an important aspect of SCB. In this regard, SCB has a dedicated HSE department with several experts, who conduct internal audits and coordinate external audits. SCB participates in audits for HSE management systems EMAS (European), ISO14001 (environment), OHSAS 18001 (occupational safety and health), ISO 50001 (energy) standard. Figure 5 summarizes some of the rules, standards and instruments that HSE maintains at SCB. The specific HSE policies set at SCB must be published on their website. Whenever these policies go against European regulations such as REACH, for example in the special cases where the use of a solvent like dichloromenthane (REACH requires substitution of solvents such as dichloromethane (CH_2Cl_2)) SCB must seek special permission.

Bayer AG is a member of the Responsible Care® initiative by ICCA. Responsible Care® is a voluntary commitment by the global chemical industry to drive continuous improvement and achieve excellence in environmental, health and safety and security performance. Evonik, audits Bayer AG for its use of acetone cyanohydrin. OPCW conducted a chemical weapons audit at SCB because of its use of organic solvents (Discrete Organic Chemicals) and phosgene (possible by-product of SCB processes). The audit also looked at organic compounds that contain PSF (phosphorus, sulfur or fluorine) which are potential chemical weapons or precursors.

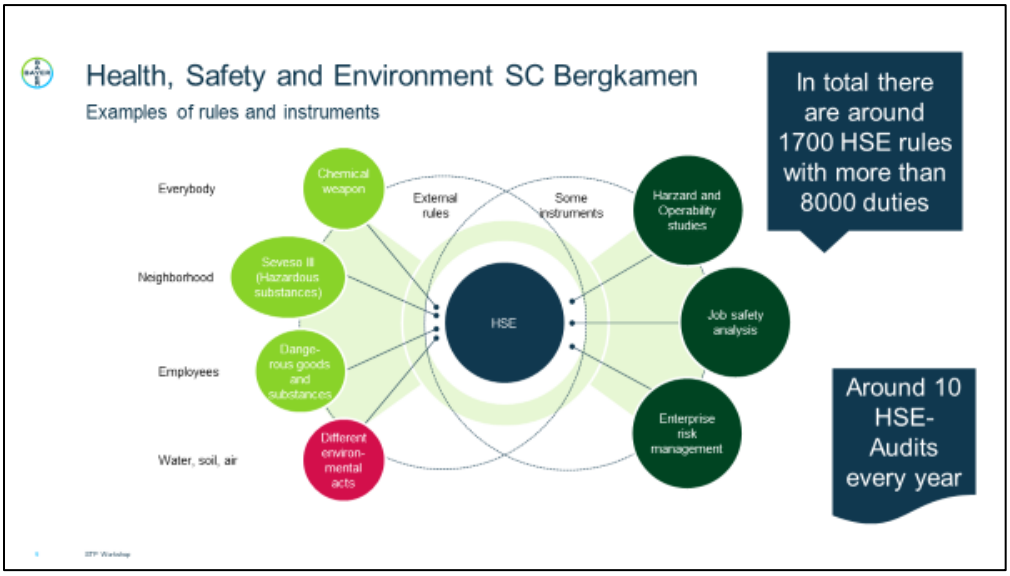

Figure 6. Heath, Safety and Environment rules and instruments at SCB (Courtesy of in der Weide)

BIMKA is the first occupational health and safety program implemented at SCB, which looks at Lost time Reportable Incident Rate (LTRIR). In 1991, at the launch of BIMKA, about 100 LTRIR were reported annually. With the launch of BIMKA Unfallfrei (no incidents) the LTRIR reported annually dropped to less than 20. Since then and with the HSE department lauching behaviour based safety, the LTRIR is now less than one per year. Behavior based safety involves eliminating

risky behaviors, encouraging safety habits and transparent observation of behaviors, giving positive reinforcements and promoting feedback culture. This safety culture is encouraged even outside the workplace. In this regard, Bayer compensates workers who are insured for incidents that occur on their way to or from work, so long as they are on their direct route to or from work.

BAYSIS is used to report incidences, injuries, process safety incidences, fire, explosions, strikes, complaints from the community and natural disasters. Transportation incidences have to be reported if these were paid for by Bayer.

3.2 HAZOP

Hazard and Operability Study or HAZOP is a systematic way to identify possible hazards in a work process. HAZOP is a common hazard analysis method for complex systems. It can be used to identify problems even during the early stages of project development, as well as identifying potential hazards in existing systems In this approach, the process is broken down into steps, and every variation in work parameters is considered for each step, to see what could go wrong. HAZOP's meticulous approach is commonly used with chemical production and piping systems (GraphicProducts, 2019).

Bayer has internal guidelines on HAZOP analysis. HAZOP is done on technical devices, equipment, reactions and processes. It is done before a new equipment is ordered and is repeated every 5 years or when the equipment is replaced.

3.3 Inventory Management System

SAP is the ERP system used at Bayer. It has two different modules (1) Inventory management and (2) Warehousing are of special interest in reference to safety and security. QA sets additional requirements which are input into SAP system, such as reporting and audit requirements. Material is tracked per drum of raw material or product.

Four people can make changes to the SAP system. Others have controlled access, such as making orders for raw materials in production. Some products such as testosterone which is prone to theft have special controls and are flagged on the SAP system as a theft risk. Testosterone is monitored in the plant all the way to the customer. An automatic email is triggered once it has been shipped to the customer. If a response is not received, the authorities are informed. However, it was noted that chemical weapons or precursors such as thionyl chloride and DOCs are not flagged on the SAP.

Testosterone, thionyl chloride, acetone cyanohydrin (audited by Evonik), DMSO, hydrogen fluoride and methyl ethyl ketone which are dual use are monitored from the moment they get to SCB all the way to their disposal or consumption. Production documentation are stored for 30 years.

3.4 Production Unit A

PUA produces 24 APIs which involves 101 synthesis steps. PUA consists of 5 units namely, Unit 2, Unit 4 north, Unit 4 South, Unit 5cy and Unit 5 cx. Each unit is made up of a specific equipment

set. Production is planned a year in advance and placed in a calendar. QA has oversight over both QC and Production, by introducing requisite regulations and ensure proper documentation for all products. GMP and HSE training for personnel in PUA is conducted four times a year.

In PUA, bromine is used in the production process, however, it is stopped from getting to the environment using brushes. It is later incinerated. Bromine “gas is very corrosive to the eyes, skin and respiratory tract” (Hanston, Baud, & Garnie, 1996). If ingested in liquid form, bromine acts as a corrosive poison. Intense burning pain throughout the gastrointestinal tract, dysphagia, vomiting, eructation of offensive vapors, and purging are due to the corrosive action of bromine liquid on the GI tract. If inhaled in its gaseous form, then bromine causes violent catarrhal inflammation of the respiratory tract. Symptoms include cough, feeling of constriction of the chest, pulmonary edema, hemoptysis, edema of the glottis and larynx, and death from suffocation (Gupta, 2016).

Loading of raw materials and collection of finished products is done in clean rooms (with positive pressure in comparison to the neighbored rooms).

3.5 Production Unit B

PUB utilizes organometallic reactions such as the Simmons-Smith reaction (Simmons & Smith, 1959). It uses a “methylene free radical” intermediate that is delivered to both carbons of the alkene simultaneously, therefore the configuration of the double bond is preserved in the product and the reaction is stereospecific (Charette & Beauchemin, 2001). PUB utilizes a completely closed system, therefore they do not have to register all the intermediates in the process. This saves a lot of time and costs. A completely closed system does not require the operators to have special PPE when loading raw materials or collecting the finished product. Although the closed system is advantageous in terms of safety, loading the raw material takes much longer. Operators initially did not like the change because it slowed them down, but once they realized its’ advantage in terms of safety and time saved because one is not required to don the special PPE, they embraced it.

3.6 Production Unit E

As noted in PUB, bromination is also used in PUA to form double bonds. Similarly, precautions are taken to stop the release of bromine to the environment. Birch reductions are used in the processes.

The “Birch reduction” is an organic reaction that is used to convert “arenes” to “cyclohexadienes”. In this organic reduction of aromatic rings in liquid ammonia with sodium, lithium, or potassium and an alcohol, such as ethanol and tert-butanol. This reaction is unlike catalytic hydrogenation, which usually reduces the aromatic ring all the way to a cyclohexane (Rabideau & Marcinow, 1992).

3.7 Microbiology Plant

The Microbiology Plant conducts microbiological fermentations, which use yeast, fungi, or bacteria to replace 4 or more chemical synthesis steps, making the production processes of some APIs more efficient.

3.8 Production Unit F

Production Unit F produces imaging media such as Iopromide, Gadobutrol and Calciumbutrol. It is the newest and largest plant in SC Bergkamen. Like in other plants PUF has stainless steel or enamel lined reaction vessels.

In PUF the system is closed to the environment. Thionyl chloride which is toxic and reactive with other substances must be handled in a closed system. Leaks are checked by applying pressure, closing the system and monitoring the pressure. The pressure drop should be within the allowable limits. No QC sample is taken for the $SOCl_2$ when it is delivered; the pre-audit of the supplier ensures quality in the supply chain. The hoses used for $SOCl_2$ are double layered and constantly checked for pressure drops.

Hydrogen being an explosive hazard is also handled in a special way. Rapture disks and safety valves are used. Since it causes an explosive atmosphere, all installations in the plant are explosion proof. For this reason, regular cell phones are banned from the plant. All hydrogen reactions have a different exhaust system. Scrubbers are used to remove other substances such as ammonia and the hydrogen is released into the atmosphere.

3.9 Ground Water

European law requires that ground water analysis is performed before a chemical company is established and after every 5 years. SC Bergkamen has 50 points where ground water can be sampled. The ground water quality must be maintained or improved to meet the requirements set by law. However, the groundwater is not used for production. Municipal (potable) water is used for production, but after further purification and deionization to remove the chloride and other ions.

In case of spillage from the production which has been not contained in special tanks or a catchment area, the fire brigade must contain the spill. In such a case the soil the affected soil is dug out and taken to a special area it is temporarily stored and analyzed. If it is found to be contaminated, it is taken to a landfill or incinerated. This process is to ensure that the ground water is not contaminated by the spillage.

3.10 Incineration and Disposal Plant

SC Bergkamen has an incinerator that burns at a temperature of at least 900°C. Solvents from the production are first recovered and those that cannot be recovered (for example azeotropic mixtures) are used as fuel to produce steam. Methanol is not recovered, because it is cheaper to buy than to recover. Ethanol, ethyl acetate and other solvents are recovered.

Solids from production and sludge from the wastewater treatment plants are incinerated and produce ashes. These ashes been determined to be inert (through analysis). The inert ashes are dumped in landfills (only for ashes with less than 3% total organic content), used to make tarmac roads or used to fill salt mines.

3.11 Power Plant

SCB has its own power supply which can support the plant in case there is no power from the town grid. The power supply is therefore redundant. A steam turbine is used to generate electricity. The steam is also used to sterilize equipment in the microbiology plant.

The plant is responsible for stream supply, current supply, incineration of waste production gases, deionized water, potable water, nitrogen plant, hydrogen gas and ammonia for cooling. The power plant has 5 boilers. The boilers use energy from natural gas, fuel oil and waste liquids or gases.

The recycling of waste solvents (about 60%) saves money and the solvents are used as fuel to produce steam. The steam is produced at 5 Bar/230°C and 16 Bar/320°C.

3.12 Distillation Plant and Solvent Recovery

Bayer AG is dedicated to protecting the environment. In this regard, 60% of all the solvents used in production are recycled. Membranes are used to remove biological materials and activated carbon to remove non-biological materials. Solvents that cannot be recovered are used to produce energy in the incineration plant.

To reduce consumption of municipal water, rainwater is harvested and used for non-pharmaceutical processes such as cleaning.

3.13 Waste Disposal, Incinerator and Recovery of Sodium Iodide

Bayer AG, Bergkamen produces around 30,000 tonnes of waste annually, 14,000 tonnes are incinerated in the rotary kiln incinerator (department disposal facilities, DF) 12,500 tonnes is liquid waste and 1,500 tonnes is solid waste. Sodium iodide is recovered as a solid waste and is reused in other technical productions of external companies. The sodium iodide is not used in production because it is not pharmaceutical grade. Waste incineration produces 17% sodium iodide.

Neutralization and coagulation are used to precipitate heavy metals. Membranes are used to remove biological materials and activated charcoal to remove non-biologicals. Polymers and $FeCl_2$ are added to speed up the sedimentation process.

Other waste – as mentioned above - is incinerated in a rotating kiln or a special vessel in the power plant. Both burn at 900 degrees Celsius and above. German authorities have online access to remotely monitor, 24 hours seven days a week, the gases released to the environment after the incineration. To control minimize the formation of dioxides which form at 200 – 300°C, the kiln is cooled rapidly to 80°C.

3.14 Bayer AG Training Centre

Bayer SCB has a training centre that is located within the plant. The centre has several mini plants which are used to train the students. The program is a 3-year apprentice program focusing on practical knowledge. The students graduate as Chemical Technicians (Not a Chemical Engineer) after sitting for a National Exam offered by the German authorities.

3.15 Facility Management, Site Security, Cyber Security and Emergency Response

Bayer AG, Bergkamen employs a layered security approach with regular patrols inside and outside the perimeter fence. CCTV is also used to monitor the whole plant with drone detection. Cameras with heat detectors are installed all around the plant. The Security can shut down all the doors remotely if the need arises for example in the case of a terrorist attack. Access control is employed using electronic ID cards for visitors are employees. All visitors to the plant are required to watch a video and pass a safety exam before they are granted access to the plant.

A public address system connected to all buildings and production units is used to convey emergency messages. Emergency messages can also be sent to all employees via the intranet. Bayer AG has a fire brigade with state-of-the-art equipment to fight various types of fires, including chemical fires. The fire brigade also serves the community when called upon. In the event of a crisis, Bayer AG, has a dedicated crisis center with a pre-assigned crisis team. The crisis center has phones, computers, meeting rooms, televisions and other equipment dedicated to crisis management. The crisis team trains every two weeks and their roles mimic those of the local government authorities for ease of communication.

In 2017, several organizations were attacked by the Wanna Cry virus which encrypted their data and asked for payment in bitcoin before decrypting the data. This and other cyber-attacks require organizations to take Cybersecurity seriously. Bayer maintains a full time IT team. Its process systems are on a different platform from the world wide web to minimize the possibility of compromise from a hacker. Furthermore, several backups on MS Windows® and UNIX® are also maintained. An elaborate firewall and partitioning system are also used as an additional measure to prevent cyber threats. Furthermore, the process control system has a plug that can be disconnected from the network and allows it to finish a process but does not allow the start of a new process.

Employees receive regular training on internet security, phishing emails and other cybersecurity matters. KeyPass is used for password management and YubiKeys to protect access to phones and computers.

3.16 The Safety Training

At Bayer, all the production plants were considered chemical facilities. The following reminders and signs were posted all over the production area: Wear a helmet and safety glasses! Do not use your cell phone!

1. Switch off electric devices, which are not explosion proven! Do not touch pipes or vents!
2. Keep a distance from the walls inside the elevator! Do not smoke! Use handrails!

Figure 7. Safety signage in production facilities

All the production was done in a closed system, such that no raw material or product is exposed to the environment or to the workers. Clean rooms with negative pressure are used to load raw materials and collect final product (in sealed drums). The operators who load and unload raw materials or final product wear special PPE. Production Unit B (PUB) has a completely closed system. In this unit, the operators do not wear special PPE. However, standard PPE that is shoes, jacket, helmet and goggles are still worn.

3.17 Safety Culture

SCB has put in a lot of resources and time to instil a safety culture among all personnel. Senior management receives regular training to lead the safety culture at SCB. Behavioural safety is a continuous process that involves technology, HSE management systems and human factors (Figure 7). Implementation of behavioural safety involves structured implementation as shown in figure 8.

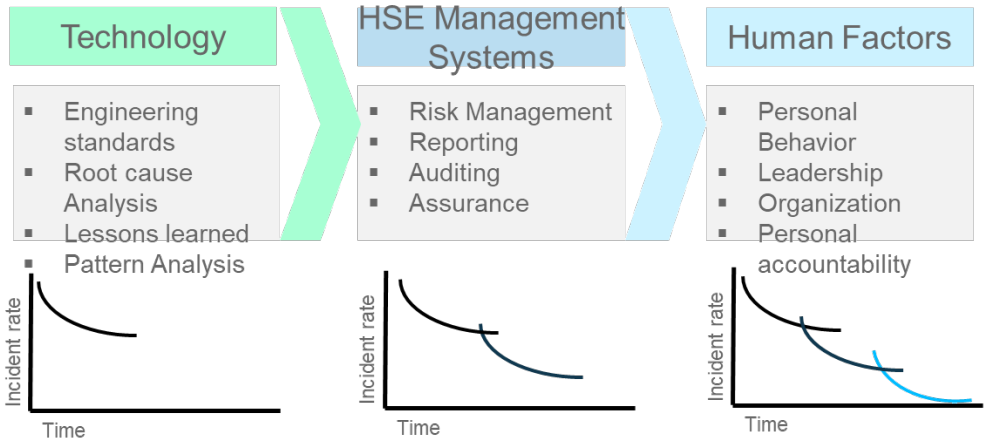

Figure 8. Safety levels: Behavior Based Safety as a continuous improvement

In a mature safety culture, The entire workforce constantly, strongly pursues the identification and control of hazards; Employees at all levels are equally comfortable stopping each other when at-risk behaviour is observed and recognizing each other when safe behaviour is observed; No one is blamed for near misses or incidents; instead systemic causes are identified, changes are made to prevent those near misses and incidents from happening again; The fear of discipline which

drives under-reporting and reduces involvement has been driven out of the culture. Employees trust that what they bring up will not be used against them.

Figure 9. Structured implementation of the Behavioral Safety Program

3.19 AUDITS

All manufacturing is done under cGMP. Several internal and about 15 external audits are conducted annually by various stakeholders including German authorities, US Federal Drug Administration (FDA), Japanese authorities, Korean authorities, Russian authorities, Evonik and OPCW. Other audits include those on energy management, EMAS audit for environmental management by external auditors, IED (Industrial Emissions Directive) by inspections by local authorities.

For example, every boiler must be checked yearly to ensure that all safety valves and feature are operational. Inspection of the boilers interiors is done every 3 years. Pressure tests are conducted every 9 years. There is a differentiated check system for all machines and vessels. What has to be checked in a special interval is prescribed in different external and internal rules.

3.20 CONTROLLING EXOTHERMIC RUNAWAY REACTIONS

The main causes of runaway reactions are (1) Inadequate understanding of the process chemistry and thermochemistry, (2) Inadequate engineering design for example heat transfer system, agitation system, control systems and safety back-up systems, (3) Inadequate operational procedures, including training and (4) Human factors. At Bayer, the following factors are considered to runaway reactions, these are; (1) Equipment (2) Organization measurer (3) behavioral measures and (4) process design an accident therefore means there is a gap in one of the fours factors. It is therefore important to have inherent safety in all the processes. In this regard, all reactors are standardized to control runaway exothermic reactions. For example, all reactors are standardized such that all the dosing valve V25 is the same for all reactors in all plants. All reactors are built using stainless steel or enamel lined.

By controlling stirring rate, temperature, pressure and dosing rate, exothermic runaway reactions can be controlled. Endothermic reactions do not pose a risk of running away. In this regard, pressure release valves are designed to release both gas and liquids. Another measures that can be used to control runaway reactions is to add the reactant once the reaction temperature has been attained and to use a semi-batch process.

Figure 10 shows some of the safety features that are standard for all reactors at SCB. An added advantage to this feature is that the same programming recipe can be duplicated for all reactors. To improve safety further, all emergency switches are doubled (have redundancies) i.e. S_Z, T_Z, P_Z such that is one fails, the dosing is stopped automatically. For example, when the P or T go about the set temperature as in the case of an exothermic reaction, V25 (dosing valve) is switched off automatically. In case the stirring rate (S_{Z+}) is too slow V25 shuts down. Safety Integrity Level 1 or 3 requires that the safety valves and switches are doubled. Overflows are connected to catch tanks to stop the overflows from affecting the environment. The reactors are designed to withstand low pressures and temperatures.

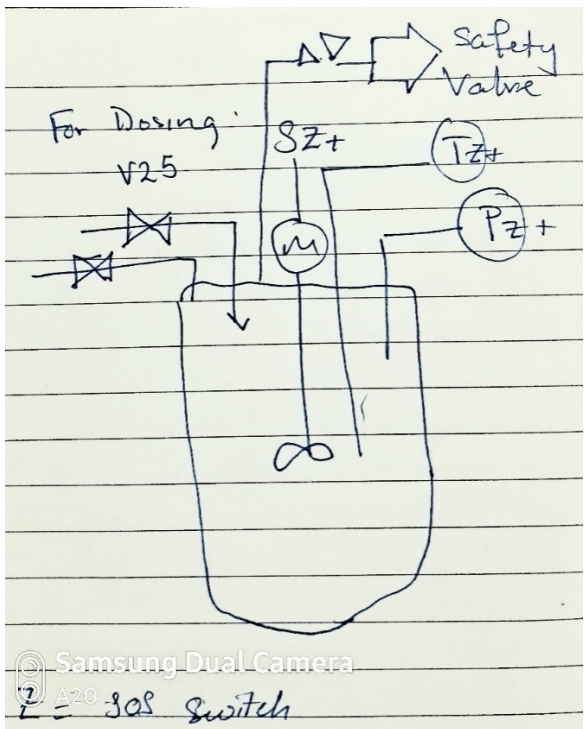

Figure 10. Schematic diagram of a reactor with safety features to control exothermic runaway reactions

4.0 After Action Plan from the Lessons Learnt

After successfully completing the STP Fellowship training program, the following is an outline of how I will apply the chemical safety and security lessons from SCB.

4.1 At the Technical University of Kenya

1. Update the Bachelor of Technology in Industrial Chemistry Curriculum at the Technical University of Kenya (TUK), School of Chemistry and Material Science (SCMS), to incorporate

production process aspects learnt at SCB such as HAZOP, Responsible Care, cGMP, ISO Certification and Safety Data Sheets [**March – December 2020**].

2. Introduce an electronic Inventory Management System at the SCMS to manage the chemicals used for teaching and research [**February – March 2020**].
3. Give a presentation to the staff and students of SCMS during the weekly seminar series on the lessons learned during the IUPAC STP Fellowship training [**March 2020**].
4. Submit a proposal to potential donors such as DFID or IFS for a research study to on the discharge of API's in water bodies in Kenya [**August 2020**].

4.2 At the Kenya Chemical Society

1. In collaboration with the Kenya Association of Manufacturers (KAM), plan for a training on Responsible Care© for Chemical Industries in Kenya [**May 2020]**.
2. Give an oral presentation at the planned Kenya Chemical Society International Conference of the Kenya Chemical Society [**August 2020**].
3. Work with the emergency first responders (police, medical and fire brigade) in Kenya through the Kenya Chemical Society to form an association of hazmat responders in Kenya, where information exchange on chemical emergency response can be initiated [**February - August 2020**].
4. Organise a workshop to sensitise chemical industry in Kenya on supply chain safety and security, "Know Your Customer" [**June 2020**].

4.3 Nationally (Kenya)

1. Engage (send an email) the German Academic Exchange (DAAD) Kenya Office to support Kenyans to get practical industrial training at Bayer Training Centres and other similar training institutions in Germany, on process management [**March 2020**].
2. Engage (send a letter) the Kenya Government and Education stakeholders on the need to improve chemical safety in high schools, especially during the chemistry National Examinations. In the last National Exams, xylene was used as a reagent in one of the practical exams and it was alleged that several students were exposed to the chemical and had to seek medical attention [**March 2020**].

5.0 What Went Well or Not during the Training at Host Company

1. The training at SCB was very elaborate, detailed and very beneficial. All the personnel I met were very committed and dedicated. I engaged with senior managers who were well prepared and escorted me around the different facilities as they explained their operations. They also constantly reminded me to hold the rails as I when going up or down a flight of stairs and other safety practices. There is a very good safety culture at SCB.
2. To better achieve the objectives of the training as stipulated by COCI STP, there is need for intimate discussion/coordination between the host company and the training coordinator.

3. The host ensured that the trainee was engaged during the weekend, volunteering his time to show him historic and cultural sites in Kamen and Dortmund.
4. Documents and PowerPoint slides were printed in German; this posed a challenge to the trainee who was only conversant in English.
5. The inventory management system, SAP, flags high theft risk materials such as Testosterone, but does not flag dual use chemicals such as thionyl chloride or the organometallics. I propose that SAP also monitor chemical dual use materials and also send alerts as is done for testosterone.
6. The accommodation provided in Kamen, Germany was not suitable for study and had unstable WIFI connectivity. The staff at the hotel were not conversant with English, making communication with them a challenge.

6.0 Suggestions on How to Improve the STP Program

1. The COCI STP program which focuses on safety and security training could be twined with the OPCW's Associate Program, which is offered annually, so that during the industrial section of the OPCW training interested associates may undertake the STP. This collaboration between IUPAC COCI STP and the OPCW Associate Program may save costs for both organizations while giving the trainees both chemical safety and chemical security expertise.
2. The COCI STP Fellowship training was well organised. However, the roles of the various organizations supporting the program (IUPAC COCI, CRDF and SCB) seemed at times unclear. For example, it was not clear who was to handle the STP Fellowship trainee's meals (dinners and meals on weekends) and incidentals. For future STP Fellowship training programs, I propose that this is made clear, in writing, to the trainee and to the host company before commencement of the training program.
3. IUPAC COCI STP may consider partnering with organizations such as DAAD (German Academic Exchange Program) and other similar organizations which supports post-graduate training in developing countries, to support the STP in the future.

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