# MASTER'S THESIS

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# A STUDY OF THE ATEX CERTIFICATION PROCESSES AT A MEDIUM-SIZED COMPANY.

Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Engineering, Espoo 16th October 2007.

Supervisor Professor Raimo Sepponen

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# Preface

I would like to thank Professor Raimo Sepponen for supervising my thesis.

I also want to show my gratitude to the employees of Savox Communications and Savox Manufacturing Services for sharing your knowledge with me. Especially my instructor Mikko Hellström and Kai Leppälahti deserve additional thanks for reading and commenting my work. I could not have written this without everybody's help.

Above all I would like to thank Lauri Westling for his endless support through the process of writing this thesis. Your help and guidance was priceless. Thank you for everything!

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Tutkimuksen tarkoitus oli tunnistaa keskikokoisen yrityksen ATEX sertifiointi prosesseissa olevat ongelmat. Paitsi tunnistaa ongelmat, tarkoitus oli ehdottaa toimenpiteitä ongelmien ratkaisemiseksi. Osana prosessia nimettiin myös vastuuhenkilöt.

Käytetyt menetelmät perustuivat pääasiassa henkilökunnan haastatteluihin ja yrityksen prosessien sekä asiaan liittyvien viranomaisvaatimusten tutkimiseen.

Tärkeimpiä havaintoja olivat puutteet henkilökunnan osaamisessa ja tietämyksessä. Lisäksi huomattiin, ettei yrityksen laatujärjestelmä ota riittävällä tasolla huomioon ATEX-vaatimuksia. Näistä huomattavimpia oli mm. tuotekehitysprosessi. Laatujärjestelmän puutteiden lisäksi tuli vielä huonosta valvonnasta ja henkilökunnan asenteista johtuvat ongelmat.

ATEX-vaatimuksien täyttämiseen liittyvät ongelmat tunnistettiin, ja niihin löydettiin vähintään tyydyttävät ratkaisut. Samalla nimettiin vastuuhenkilöt uusille prosesseille. Henkilökunnan haastatteluista ja ATEX-standardin tuntemuksesta oli suuri merkitys työn onnistumisen kannalta.

Avainsanat: atex sertifiointi, räjähdysvaarallinen atmosfääri

HELSINKI UNIVERSITY OF TECHNOLOGY ABSTRACT OF THE MASTER'S THESIS

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The purpose of this study was to identify the dilemmas associated with the ATEX certification processes at a medium-sized company. Furthermore, the aim was to suggest recommendations and actions for solving the acknowledged problems. The responsible agents were also determined.

The problem and solution seeking method was based on having dialogs with the employees of the company and on studying the processes of the company as well as the demands of the authorities.

To name few of the discoveries, there is a lack of ATEX competence among the staff of the company and the suppliers. Also, the project management system does not include ATEX processes. A few other ATEX processes are not sufficiently defined either. Furthermore, the checklists are not always followed. Lastly, the staff has different strategies when it comes to ATEX issues.

The problems were identified and the solutions were found to a satisfactory level. The responsible agents were also named. The interviews proved to give good results. Personal experience and the ATEX directive and standards were also crucial to the study.

Keywords: atex certification, explosive atmosphere

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Avsikten med denna studie var att identifiera problemen i samband med ATEX certifierings processerna på ett medelstort företag. Syftet var även att ge förbättringsföreslag för att lösa de identifierade problemen. Ansvarspersonerna utnämndes även.

Metoderna för att identifiera problemen samt lösningarna baserade sig på intervjuer av de anställda och på forskning av företagets processer samt myndigheternas krav.

För att nämna några av upptäckterna: det saknas ATEX kompetens hos de anställda, projekt förvaltnings systemet behandlar inte ATEX processer, även andra ATEX processer är inte tillräckligt definierade, minneslistorna följs inte alltid och de anställda har olika strategier gällande ATEX frågor.

Problemen identifierades och lösningarna hittades till en tillfredställande nivå. De ansvariga personerna utnämndes även. Intervjuerna visade sig ge goda resultat. Personlig erfarenhet samt ATEX direktivet och standarderna var också viktiga för studien.

Nyckelord: atex certifiering, explosionsartad atmosfär

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# SYMBOLS AND ABBREVIATIONS

| | |
|---|---|
| ATEX | ATmosphère EXplosible |
| BoM | Bill of Material |
| *C*i | Maximum internal capacitance |
| *C*o | Maximum external capacitance |
| CSA | Canadian Standards Association |
| ECR | Engineering Change Request |
| FM | Factory Mutual |
| HW | Hard Ware |
| *I*i | Maximum input current |
| *I*o | Maximum output current |
| IEC | International Electrotechnical Commission |
| *L*i | Maximum internal inductance |
| *L*o | Maximum external capacitance |
| M1, M2, etc. | Milestone 1, Milestone 2, etc. |
| NB | Notified Body |
| NPI | New Product Introduction |
| ODM | Original design manufacturer |
| OEM | Original equipment manufacturer |
| *P*i | Maximum input power |
| *P*o | Maximum output power |
| PCB | Printed Circuit Board |
| SMS | Savox Manufactring Services Oy Ab |
| *U*i | Maximum input voltage |
| *U*o | Maximum output voltage |
| UL | Underwriters laboratories |

# 1 INTRODUCTION

## 1.1 Background

An explosive atmosphere is a mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapors, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture. [1]

The number of areas classified as having potentially explosive atmosphere, such as oil/gas production plants and mines, are increasing. There are at least 48 ways in which an ignition can be initiated, for example hot surfaces, friction, impact, exhaust products from engines, chemical reactions, compression and adiabatic expansion of one gas. [2]

Consequently, the market for devices intended for use in potentially explosive atmospheres has grown. These devices are often referred to as Ex apparatus or Ex equipment. The European market for such equipment is estimated at 3 Billion euros per year. [3]

To protect citizens and the end-users the European Union has devised a directive that controls the construction and manufacturing of these Ex products. Linked to the directive are technical standards for different kinds of products and quality standards for the processes. All Ex products sold within the Europe Union must comply with this directive.

Ex devices must be approved and certified by an authorized representative established within the EU. This agent ensures and declares that the product complies with the before mentioned directive and the standards linked to the directive. [4] A certified product is safe to use in the designated explosive atmosphere.

It can be noted that there are few explosions known to have been caused by Ex apparatus or due to deficient standards. [5] However, accidents have occurred where properly constructed explosion protected equipment was incorrectly worked. [6] It is therefore important, besides designing and manufacturing the apparatus properly, to also operate the device correctly.

The manufacturer of equipment intended for use in potentially explosive atmospheres is responsible for the conformance of the products. In other words, the manufacturer must ensure that the quality provisions of the directive are met and that the products follow the requirements of the technical standards.

## 1.2 The Directive

This is a brief look at the directive that regulates the processes examined in this study. This section explains the concepts used in this report as well as the different product classes. Furthermore, a short description of the responsible person of the supplier and of the certification agent is given.

### 1.2.1 General

Equipment and Protective systems intended for use in Potentially Explosive Atmospheres Directive 94/9/EC, hereafter known as the Directive, was approved on 23 March 1994 by the European Parliament and the Council of the European Union. The Directive is named after the French "*ATmosphère EXplosible*" and it has been mandatory since 1 July 2003.

The aim of the Directive is to allow free movement of approved and marked products within the European Union. Member countries set the provisions of the Directive into their legislation. Subsequently, manufacturers within these countries, who apply these provisions, can freely put equipment in the scope of the Directive on the European market.

The Directive applies to all manufacturers within the Member States of the European Union, who manufacture and put to market equipment intended for use in explosive atmospheres. The Directive is aimed at electrical and non-electrical equipment, protective systems, components and safety, controlling and regulating devices intended for use in potentially explosive atmospheres.

### 1.2.2 Concepts

An explosive atmosphere is a mixture with air, under atmospheric conditions, of flammable substances in form of gases, vapors, mists or dust in which, after ignition has occurred, combustion spreads to the entire unburned mixture. A potentially explosive atmosphere is an atmosphere, which could become explosive due to local and operational conditions. Equipment means machines, apparatus, control components and detection or prevention systems. Protective systems are units, which are intended to halt explosions. Components are any items essential to the functioning of a system but with no independent function. [7]

> Ex component: part of electrical apparatus or a module, which is not intended to be used alone and requires additional consideration when incorporated into electrical apparatus or systems for use in explosive gas atmospheres
>
> ATEX: *ATmosphère EXplosible*. This abbreviation is used very liberally to describe a product, process etc. associated with the ATEX directive.

The Company: the designer, manufacturer and supplier of ATEX certified products and services.

A normal product, process etc.: a non-ATEX product.

### 1.2.3 Equipment classification

The equipment is categorized into two groups, group I and II. Group I comprises equipment intended for use in potentially explosive atmospheres underground, such as mines. Surface installations (of mines) endangered by firedamp and/or combustible dust also belong to this group. Group II comprises equipment intended for use in potentially explosive atmospheres other than underground. The groups are further categorized into two, respectively three sub categories; see Table 1.

**Table 1. ATEX device groups and categories.**

| Equipment-group | I Underground | | II Above ground | | | | | |
|---|---|---|---|---|---|---|---|---|
| Category | M1 very high level of protection | M2 high level of protection | 1 very high level of protection | | 2 high level of protection | | 3 normal level of protection | |
| Atmosphere | | | Gas | Dust | Gas | Dust | Gas | Dust |
| Use device in zones | | | 0,1,2 | 20,21,22 | 1,2 | 21,22 | 2 | 22 |

Potentially explosive environments are categorized into three zones depending on the presence of the explosive atmosphere. In zone 0 (or 20) the explosive atmosphere will occur continuously or for long periods, in zone 1 occasionally and in zone 2 rarely or for short periods. The device categories and corresponding zones can be seen in Table 1 and an example of zone mapping in Figure 1.

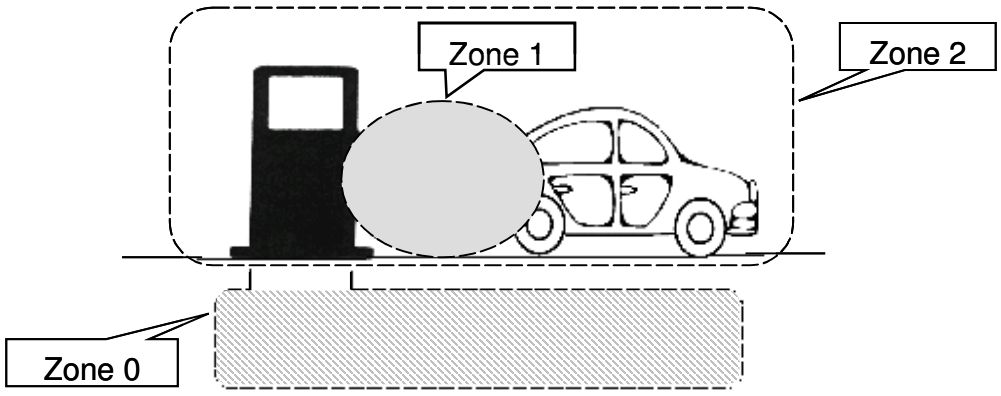


**Figure 1. Equipment operating zones.**

### 1.2.4 The ATEX responsible person

The Company must appoint an authorized person that heads the ATEX. This ATEX responsible person oversees and approves the ATEX processes and documents. He is overall responsible for seeing to that ATEX products are properly certified and approved. Furthermore, he is responsible for making certain that the customer receives the instructions to allow proper and safe use of the product.

### 1.2.5 The Notified Body

The Notified Body (NB) issues the ATEX certificate to the manufacturer. It performs test and examines, whether the technical solutions applied meet the provisions of the Directive and the product standards. Approved products receive a product certificate. The NB also inspects the quality system of the Company. Approved companies are issued a quality certificate. All member countries have at least one Notified Body. The NB in Finland is VTT and the identification number is 0537.

## 1.3 Standardization

There are approximately 60 active standards under the Directive. The relevant standards for this study are the quality system implementation standard EN 13980 and the product requirement standards EN IEC 60079-10, EN IEC 60079-11 and EN IEC 60079-14. A brief view of these standards follows.

### 1.3.1 EN 13980

The title of this standard is Potentially explosive atmospheres- Application of quality systems. The document contains the requirements for the quality management system for equipment intended for use in potentially explosive atmospheres. It is intended for manufacturers, the Notified Body and the authorities. It is also used as a base for the quality inspection that the Notified Body performs on the Company. The standard is a supplement of the quality control standard ISO 9001:2000 and follows the chapter structure.

### 1.3.2 EN IEC 60079-0

This standard is named Electrical apparatus for explosive gas atmosphere - General requirements. The standard specifies testing and marking of electrical apparatus and Ex components intended for use in explosive gas atmospheres. This is the primary standard that the other EN IEC 60079-standards complement. Table 2 shows the temperature classes according to EN IEC 60079-0.

**Table 2. Temperature classes**

| Temperature classes | Max surface temperature |
|---|---|
| T1 | 450 °C |
| T2 | 300 °C |
| T3 | 200 °C |
| T4 | 135 °C |
| T5 | 100 °C |
| T6 | 85 °C |

### 1.3.3 EN IEC 60079-11

The title of this standard is Explosive atmospheres- Equipment protection by intrinsic safety "i". This standard is applicable for the construction and testing of intrinsically safe apparatus intended for use in an explosive gas atmosphere. Table 3 shows the different intrinsic safety categories according to this standard. There are several other categories, for instance flameproof enclosure and oil immersion groups.

**Table 3. Intrinsic safety categories for Group II gas atmosphere equipment.**

| Method of protection | Code letter |
|---|---|
| Intrinsic safety permitted for Zone 0, depending on the device category | ia |
| Intrinsic safety, sufficient for Zones 1,2 | ib |

### 1.3.4 EN IEC 60079-14

This document has the title Electrical apparatus for explosive gas atmospheres – Electrical installations in hazardous areas (other than mines). This part contains the specific requirements for the design, selection and mounting of electrical installations in explosive gas atmospheres. Table 4 shows the different explosion groups according to this standard.

**Table 4. Explosion groups for Group II equipment**

| Explosion group | Ignition properties |
|---|---|
| IIA | Low degree of hazard (e.g. propane) |
| IIB | Medium degree of hazard (e.g. ethylene) |
| IIC | High degree of hazard (e.g. hydrogen) |

## 1.4 Product Markings

Approved ATEX equipment is marked a sign of approved certification. The marking also allows traceability. The label must legible and durable. It must contain the name and address manufacturer, the serial number, the name of the standard and year of construction. The standards mentioned above also have stipulations concerning marking of ATEX products. The following markings are mandatory according to different standards.

### 1.4.1 CE marking

The CE marking on the product states that the product has been manufactured and assessed in conformity with all the requirements of the Directive. The identification number of the notified body follows the CE mark; see Figure 2.

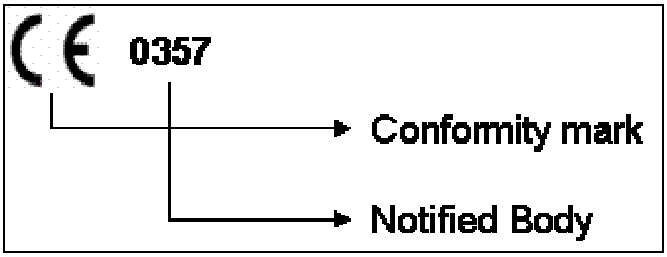


**Figure 2. Example of CE label.**

### 1.4.2 Identification in accordance with the Directive

All ATEX products must have the explosion protection marking, followed by equipment group (I or II), category (1, 2 or 3) and type of atmosphere (Gas or Dust), see Figure 3. Table 1 lists the groups, categories and atmospheres.

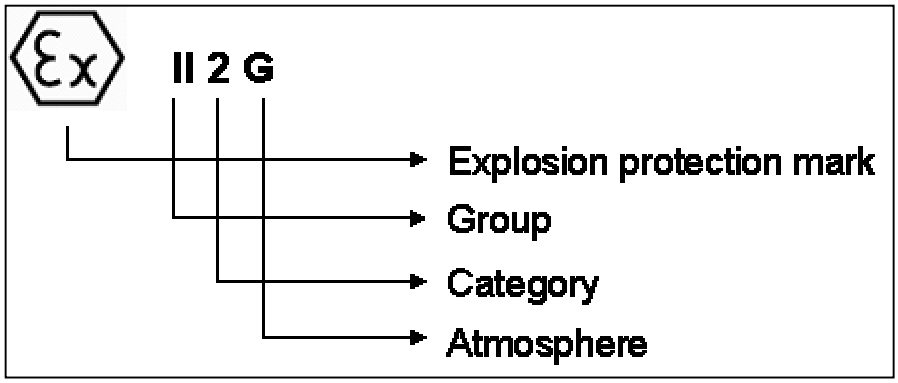


**Figure 3. Example of ATEX explosion protection label**

### 1.4.3 Identification in accordance with EN 60079

The standard group EN 60079 states that the markings in Figure 4 must be present on the product. The markings consist of 'Ex' for explosion protection, type of ignition protection (14 different types), the explosion group (I, IIA, IIB or IIC) and the max surface temperature of the product (T1-T6). See Table 2, Table 3 and Table 4 for more information on the categories.

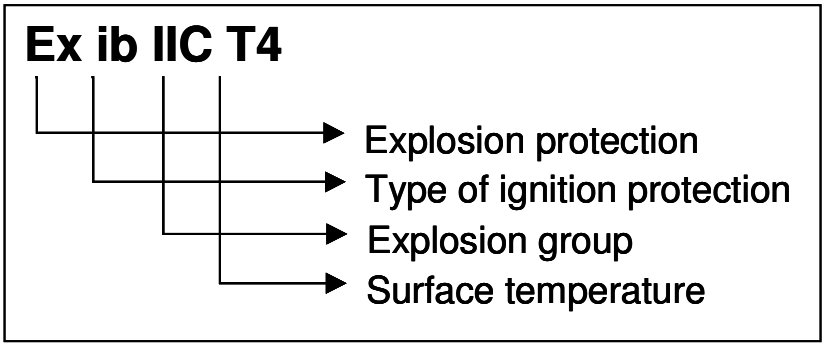


**Figure 4. Example of identification in accordance with EN 60079-0.**

### 1.4.4 Housing protection class

IP stands for an International Protection and the standard indicates the protective characteristics for equipment. The standard is based on IEC60529. The first digit, 0-6, states how well the apparatus can resist the entry of solid objects and the second digit, 0-8, the entry of water. This marking is not mandatory for all product classes.


**Figure 5. Example of IP marking**

### 1.4.5 Other markings

The equipment may possibly have additional mandatory markings such as warning signs. For example, battery driven equipment might require a sign warning the user not to change the batteries in a possibly explosive atmosphere. If the product may not be plugged or un-plugged in possibly explosive atmosphere, a warning on the product can be mandatory.

### 1.4.6 Label example

An example of an ATEX product label can be seen in Figure 6. SAVOX 400/HT981 is the name of the product. VTT 05 ATEX 009X is the designated name of the certificate, where 05 represents the year 2005. The serial number and year of construction are missing from the label and must in this case be presented on another label. The IP class can be left out from the label as long as it is conveyed in the users manual, for instance.


**Figure 6. Example of an ATEX product label**

## 1.5 PURPOSE OF THE STUDY

ATEX products have to be tested, approved and certified at a Notified Body before being released on the market. The ATEX certification process at Savox Communications is very time-consuming at the present time. This study focuses on this point. The purpose of the study was to examine the existing ATEX processes of Savox Communications and achieve the following objectives:

- The dilemmas associated with the ATEX certification processes are identified. These are problems that prolong the certification process.
- Furthermore, recommendations and actions for solving the acknowledged problems are suggested.
- The responsible agents for executing the recommended actions are also determined.

The scope of this study focuses on the departments of Savox Communications Oy Ab as well as the suppliers of the company. Savox Communications Oy Ab provides communication solutions for safety equipment used in hazardous jobs. The products are used by military, police, fire, rescue, and industrial professionals [8].

# 2 MATERIALS AND METHODS

This section covers the materials and methods used in this study. The purpose of the study was to examine the ATEX processes of Savox Communications, e.g. the Company. The processes are lead by persons at the Company. Therefore, the main problem seeking method was to interview the staff of the Company as well as the relevant associates. Some dilemmas surfaced frankly by dealing with the daily processes.

The method of finding solutions to the problems was partly based on having dialogs with the employees and the project teams. A years worth of personal expertise through working with ATEX issues as well as the expertise of the employees was a valuable source when tackling the dilemmas. Furthermore, the Directive and standards were used as support when finding the solutions for the problems.

## 2.1 The examined sections

The study was divided into different sections, basically according to the departments of the Company. To get a good overview of the problem, all parties involved in ATEX issues at the Company were dealt with. The departments were examined separately and the responsible persons were interviewed independently. The interviewed agents are experts in his or her area.

### 2.1.1 The Customer and the Sales Department

ATEX issues were discussed with a representative of the sales department. The questions related to knowledge about ATEX issues amongst customers and sales persons. The incentive was to learn what information they need to be able to purchase or sell ATEX products. The aim was also to inquire about the selling process of ATEX products as well as ATEX records created in the process.

### 2.1.2 Project Management

The project manager was interviewed concerning the project management process. The aim of the discussion was to learn about project timetables and resources. Furthermore, it was important to learn how the project manager takes ATEX products and processes into consideration when planning the project timetable and forecasting the project workload.

### 2.1.3 NPI

New Product Introduction processes were discussed with the NPI responsible person. The questions mostly relate to product part lists and production documents. The motive was to learn how the quality control for ATEX documents is managed and how the documentation responsible receives the necessary information.

### 2.1.4 R&D

The questions discussed with the representative from the research and design department mostly dealt with the different actions performed between milestones. The milestones are defined in the project handbook of the Company. The inquiry was based on the process flow of a non-ATEX product. The idea was to try and figure out what different branches an ATEX product should have in the flowchart. The outlines of the product and technical specifications were also discussed.

### 2.1.5 Documentation

The technical writer of the Company was interviewed concerning the documentation process. The product documents are an essential part of the certification process. Therefore the incentive was to learn about the documentation process for ATEX documents. The aim was also to find out what extra documents have to be created for an ATEX product.

### 2.1.6 Sourcing

The sourcing process for ATEX products was discussed with the sourcing manager. The aim was to examine how an ATEX critical supplier is assessed before being chosen and what skills and knowledge the Company requires of the suppliers concerning ATEX issues.

### 2.1.7 Suppliers

The processes at a supplier were researched by visiting the production facilities and interviewing the production manager. This supplier delivers assembled ATEX critical circuit boards to the Company. The visit included getting familiarized with the factory and every process from material purchasing to shipping of the finished product.

The aim of the inspection was to assess whether their processes meet the quality standards of the Company. The aim was also to examine how well they learn from mistakes and how able they are to adapt their processes to overcome problems and improve the quality of the products.

### 2.1.8 Production

Relevant persons of the production unit of the Company were interviewed. The interesting aspect of the activities of the production unit was the process flow for ATEX products. The motive was to gain insight into every production step beginning at purchasing to the finished product. Interesting was also the differences in the process flow for ATEX and non-ATEX products.

### 2.1.9 Product Tailoring

The person responsible for product tailoring and demonstrations was interviewed. The questions mostly dealt with the different steps in the tailoring and demonstration processes. The incentive was to gain knowledge of the tailoring and demonstration processes and how the ATEX cases are certified. The aim was also to determine how the processed are controlled and what kind of checklists are used.

### 2.1.10 Auditing

The ATEX auditing process was examined by assisting in the planning of and by attending three audits. The first one took place at Savox Manufacturing Services, the production unit of Savox Communications. The second audit was at the main circuit board subcontract manufacturer of Savox Communications. The last one was at a plastic part supplier. The auditing process were observed and assisted in on all occasions. The motive was to determine whether the audit process is sufficient and efficient enough to identify and correct problems in the production processes.

### 2.1.11 The ATEX Responsible Person

ATEX issues were discussed with the ATEX responsible person. The questions dealt with ATEX projects and processes. ATEX product classes and ATEX criticality were also agendas. The aim was to acquire knowledge of the duties of the ATEX responsible person of the Company.

# 3 RESULTS

This chapter reports the results of the inquiries. Most of the information is materialized from the interviews. Part of the information is previous knowledge. The chapters in this section follow the structure in the Materials and Methods-section, i.e. according to the interviews.

The study produced nine interviews. The protocols are found as attachments 1-9. The interview subject and the interviewer have signed each document. Attachment 10 is a list of the ATEX documents resulting from the actions and processes described in this chapter.

## 3.1 The Customer and the Sales Department

The interviewed agent was Mikael Westerlund, head of the sales department of the Company. The protocol can be found as Attachment 1.

### 3.1.1 The customer

The clients present their product needs. When it comes to ATEX products, they decide the product categories and other ATEX specifications. This is based on the ATEX category and the output values of the radio. Their needs are conveyed to the sales representative and the sales department.

### 3.1.2 The sales process

The basic sales process is the same whether the product in question is ATEX or not. The process flow is described in the quality handbook and an ATEX case follows the same course. The sales department is responsible for preparing the mandatory business case before a new project is approved. If the project involves ATEX products, it can be mentioned in the business case. The ATEX responsible does not have to be consulted at this point.

### 3.1.3 ATEX competence

Each member of the sales team is briefed on ATEX issues before commencing his or her tasks. They must learn and understand the basics of the Directive. Furthermore, it is important that they know what product classes and categories there are as well as what environments the different products can be operated in.

## 3.2 Project Management

The interviewed agent was Antti Ranta-aho, Project Manager at Savox Communications. The protocol can be found as Attachment 2.

### 3.2.1 Project milestones

The project process is divided into design phases with specific milestones in between. The marketing and sales process begins in the period before M0 (Milestone zero). The project itself begins at M0. The project ends at M5 when the product and production documents are released for production. The milestones and design phases are defined in the project handbook of the Company.

### 3.2.2 ATEX project management

The existing project management system is quite new to the Company. No ATEX projects have yet been carried out according to the existing project management structure. This is something that has to be developed. Schedules must be modified so as to take ATEX issues into consideration. Furthermore, the persons involved in the project must be trained with the relevant ATEX issues.

### 3.2.3 The project timetable

The preliminary timetable is made in connection with the business case, before Milestone M0. It is then revised in the technical specification phase, before Milestone M1. If required, updates can still be made after this. The project manager maps out the workload of the project and determines the resources needed to finish the project. The timetable is created on these grounds.

The timetable should be tight but realistic. We have to consider the customer and the end-user and their wish for a quick lead-time. Most importantly, we need to have the basic project management processes in hand before we can take more long-term aspects into consideration. For example, if the product being designed is not ATEX, we should concentrate on quickly getting the product on the market. We should not concentrate on needlessly designing the product with ATEX readiness.

Concerning coming ATEX projects, some things have to be taken into consideration when planning the timetable. We need to be able to determine the amount of time the certification process will take at the Notified Body, in other words, the workload schedule of the NB. We must also know what additional documents are necessary for certification.

## 3.3 NPI

The NPI processes were discussed with Patrick Söderbäck, NPI manager at Savox Communications. The meeting report is found as Attachment 3.

### 3.3.1 ATEX duties

The NPI manager sees to that the necessary ATEX markings and labels are designed. He also manages the product and production documents, by checking that all relevant documents are created. When a product has emerged from the design phase, the NPI manager provides ATEX samples for the testing and certification process at the Notified Body.

### 3.3.2 New product parts

The NPI manager is responsible for listing the parts related to a new product. The list contains part numbers and other relevant information needed for input into the component and product register. The NPI manager has sole permission to update the list when changes occur.

ATEX critical parts are marked as such. Before the list is approved the NPI manager reviews the list with at least the ATEX responsible person to ensure that all ATEX components are marked. The documentation responsible person enters the final version of the list into the register. ATEX parts are marked as ATEX components. If an ATEX part has failed to be marked in the list, it will not be marked as ATEX in the register.

### 3.3.3 New production documents

The NPI manager provides the documentation responsible person with a list of the required production documents. There are document checklists to help ensure that all relevant documents are created. ATEX products have a few additional production documents.

## 3.4 R&D

The interviewed agent was interview Mikko Hellström, head of the R&D department. This department consists of software and hardware design, mechanical design, documentation and testing as well as product approval. The protocol of the discussion is found as Attachment 4.

### 3.4.1 Milestone M0

Preceding M0 is the product specification phase during which the product specification is created. A team consisting of the project manager, a sales representative, the R&D manager and the engineers usually prepares the document. The document specifies the functional blocks of the product, including the ATEX safety functions. The document can also contain “lessons learned” from previous projects in order to avoid repeating prior mistakes. The ATEX responsible person is informed of the new ATEX project, but is otherwise not involved at this point.

### 3.4.2 Milestone M1

The technical specification for the product is created prior to M1. The document is prepared by the engineer(s). The document specifies how the functional blocks are to be realized. This includes the ATEX product class and category (sometimes already provided by the customer), temperature and IP class. Furthermore, when the ATEX requirements are known, the standards that apply for the product can be listed. The ATEX responsible person takes part in approving the ATEX product class.

### 3.4.3 Milestone M2

The period before M2 is the product design phase. ATEX products have a few additional design stages. The HW engineer designs the circuits and confirms, by calculating, that the parameters apply with the standards. Additionally, he or she lists the tests that need to be performed on the prototype. These include measuring the diodes, checking the insulation space, measuring the surface temperature (taking into account the ambient temperature), checking the insulation of the radio cable and checking the connector at the radio end. In other words, the safety elements associated with the ATEX standards are examined. When the layout and the part list are finished a prototype(s) is made and the tests are executed. (Merely functional tests are performed on a non-ATEX product).

The outcome of these measures includes the following documents: PCB schematics, BoM, specification, information of product labeling, coating, screen print and layout. In addition, a preliminary version of the safety declaration and battery test report is prepared. For the mechanical engineer the most crucial detail is the choice of plastic material. That is, anti-static material has to be used for the plastic parts.

### 3.4.4 Milestone M3

Preceding M3 is the design validation phase. At this point the safety declaration needed for certification must be finished. The safety declaration contains information on all the safety segments and features of the product.

The ATEX critical components have been marked in the BoM. The ATEX and environmental test units are available and the tests are performed. If the product is new, the environmental tests are done before the product is sent to NB, but in some cases the tests can be performed simultaneously.

### 3.4.5 Milestone M4

The period prior to M4 is the documentation and approval phase. The product is ascertained to meet the standards of the specifications and the test reports are finished. The HW engineer designs the (ATEX) PCB testing specifications for production. All ATEX critical components must undergo testing during production. The ATEX responsible files the ATEX application and composes the ATEX safety guide.

### 3.4.6 Milestone M5

Preceding M5 is the production phase. The NB has tested and approved the product and granted the certificate. The product is released and the documents are sent to the production manager. In other words, when the project enters Milestone 5, the product goes into production and the project can officially be closed.

### 3.4.7 Process control

The R&D processes are controlled with a series of milestone and document checklists. The purpose of the milestone checklists is to prevent the project from advancing without having done the necessary tasks and without creating the necessary documents. Flowcharts also illuminate the process flow and the order in which the different phases should be dealt with.

### 3.4.8 ATEX concerns

Some issues concerning ATEX designing still need improving. Firstly, the know-how concerning safety circuit connections could be more versatile. There might be better and simpler ways of implementing the required safety attributes. This also applies for the other safety segments.

The sound level is usually poor in ATEX products, compared with normal products, because the signal level has to be limited and there is not enough space for the speakers to work properly. This is a problem because the customer assumes that the ATEX product will have the same sound quality as non-ATEX version.

It would be useful for the HW engineers to get some training to improve their technical knowledge concerning ATEX products. It would give them and the rest of the Company

confidence that the technology used in the product, besides being equipped with sufficient safety features, truly is the best and most efficient possible. The product is after all the basis for a successful company.

The certification process at the NB is too slow. At the moment it is impossible to make any timetables for the certification procedure; it is too unpredictable. Either this process has to be improved or the Company should consider getting their ATEX products certified at another NB.

## 3.5 Documentation

The documentation processes were discussed with Ilse Saarinen, technical assistant at Savox Communications. The technicsl assistant is responsible for documentation. The protocol is found as Attachment 5.

### 3.5.1 The documentation process

The documentation responsible receives a request for a new part number or product. ATEX items are noted as such and products also have the ATEX classification noted. She enters the new part number(s) into the Scala, the product management system, and into the document management system. If the request is for a product, she enters both the part and the product numbers. Scala has a separate template for ATEX products/parts, which by default marks the product/part as ATEX. The document management system also has templates for product families, also separately for ATEX products.

### 3.5.2 Checking and approving

All documents have to be checked and approved by the appropriate person. There are two sets of ATEX documents, schedules and related drawings. Scheduled drawings have to be approved by the Notified Body and Related drawings by the ATEX responsible person. The ATEX responsible person sends the Scheduled drawings to the NB for approval. Approved documents are stored in pdf format to avoid changes being made to it.

### 3.5.3 ATEX production documents

ATEX products have a number of additional production documents in comparison with a non-ATEX product. The documents concern epoxy casting, the information that must be available for the customer and product marking. The additional documents and the contents of the documents are listed in Table 5.

**Table 5. Additional ATEX production documents.**

| | |
|---|---|
| Epoxy casting description | Description of what part of the loaded circuit board should be covered with epoxy. |
| Epoxy instructions | Instructions how to handle the epoxy material. |
| ATEX safety guide | ATEX product details for the customer. |
| ATEX certificate of conformance | Signed statement for customer |
| ATEX product label instructions and ATEX box label instructions | ATEX marking on product and product box |

## 3.6 Sourcing

The sourcing manager evaluates potential suppliers. The most important issue is quality management. If the supplier does not have a quality certificate they must by other means demonstrate that the processes are under control.

### 3.6.1 Training

The ATEX responsible and the sales representative train suppliers in ATEX issues. The supplier must understand the provisions of the Directive and the respective standards. They must also be able to implement the features stipulated by the standards. For example, the supplier must have product testing and marking of ATEX product in hand. The training should deal with these issues.

## 3.7 Suppliers

ATEX issues were discussed with Kimmo Turtiainen, Production manager at Darekon-Electro Ky. The protocol is found as Attachmant 7. This company is a manufacturer of circuit boards among other things and a supplier for Savox Communications.

### 3.7.1 Incoming material

When the purchased material arrives, the recipient checks that the packing list corresponds to the order and that the received material corresponds to the packing list. ATEX critical material is measured, if possible (one component per reel). For instance, one capacitor is measured per reel and compared to the datasheet. Approved material is provided with a sticker for tracking purposes and ATEX critical material with an additional ATEX sticker. Approved material is placed in storage. All ATEX

components are stored separately in an ATEX marked location to distinguish it from normal material. This system allows every component to be backtracked to which batch it came from.

### 3.7.2 The work card and component collecting

The work order is fed into the production program and the database produces a work card with the different work stages listed. Then the material list is put together. It is based on the part list that we have received from the customer. The Company sends new part lists when they are updated.

The material list is used to collect the components from the storage shelves. SMD and through-hole component are collected separately. The collected ATEX components are additionally checked by another person to confirm that they correspond to the material list.

### 3.7.3 Assembly and testing

The production workers log every completed work stage. This way the person, task and time it is recorded. There are several visual inspections during the production process. The visual inspection of ATEX critical components takes place after the SMD loading. The assembled PCBs are marked with an individual number. Defective items are documented and the report is sent to the customer afterwards.

All finished products are inspected in some way. The most important products, including ATEX products, undergo electrical tests. The ATEX critical components (not capacitors) are measured. The tolerances of the components determine the approval limits. The test results are automatically saved in a computer file. Failed test results are automatically routed to a separate file. Failed products are provided with a “Reject” sticker. When the circuit board changes, the test engineer is informed and he makes the necessary changes to the testing equipment. All test results are sent to Savox.

## 3.8 Production

The interviewed agents were Jari Makkonen, Production Manager and Kirsi Sairanen, Production Assistant at Savox Manufactring Services Oy Ab (SMS). SMS is a daughter company to Savox Communications. It is situated in Savonlinna, Finland and it is the sole production unit of the Company. The meeting document is found as Attachment 8.

### 3.8.1 Shipment order

The manufacturing process begins when SMS receives a work order from Savox Communications by e-mail. SMS checks the material and staff resources and calculates the delivery date according to that data. This information can be delivered to the customer. A material and task list is printed and the missing material is ordered from the suppliers.

### 3.8.2 Purchasing

ATEX material is marked as such throughout the purchasing process. All ATEX components in the component register are marked as ATEX. The purchase order is also marked with ATEX. The supplier marks the packing list with ATEX. SMS sends the packing list to Savox Communications.

### 3.8.3 Material inspection

The received material is inspected according to the specified requirements. The ATEX requirements are separately listed on the form. Batches with batch tracking are supplied with a traceability number code. All ATEX critical parts are batch tracked. The ATEX requirements in the inspection are seen in Table 6.

**Table 6. ATEX requirements in the incoming inspection**

| |
|---|
| Circuit boards are checked to ensure that they are marked with an Ex-label that indicates that the board has undergone necessary tests. |
| Plastic parts are checked to ensure that they are marked as ATEX (blue sticker + number of person responsible for testing the part at supplier). The material certificate that comes with every batch is also checked. This certificate is documented with the inspection form in a folder at SMS. |
| Finished device must have a test certificate of the product. |
| The first epoxy batch is complemented with a material data sheet. |
| Neoprene epoxy cast frames are checked for type, part number and revision information. |
| Other components are checked to ensure that the product and the packing list match. |

Inspected and approved ATEX components, parts and material are stored on a separate ATEX shelf. This arrangement prevents ATEX and similar normal parts from being mixed up in case the ATEX marker for some reason goes missing from the parts. The location of all parts is found in the component register.

### 3.8.4 Epoxy casting

The epoxy casting is generally done after the incoming inspection. The casting description is part of the production documents. The caster visually checks that there is enough epoxy and that there are no air bubbles too close to the components. The boards must be checked and approved by somebody other than the caster. Failed boards are supplied with an ”irregular product”-label and reported to the production manager.

### 3.8.5 Component collecting

The task supervisor prints the production documents from the document management system. Fresh documents are printed every time to guarantee revision control. The collector collects the components according to the work order. If the component is batch tracked, the collector compares the batch number on the shelf with the number in the register. While collecting other components, the collector always picks components from the newest batch to maintain FIFO. Semi-manufactured ATEX articles are located on ATEX marked shelves. The label responsible prints the serial number and ATEX labels on request by the collector. The serial number is found on the work order.

The collected product components are placed on separate shelves while waiting to be assembled. Collected ATEX product components are stored separately from normal ones on ATEX marked shelves.

### 3.8.6 Assembly and testing

The assembly worker visually checks that the item is correctly assembled. When the item is assembled, the worker applies the serial number label. All items undergo final testing. ATEX and non-ATEX product virtually undergo the same tests, but ATEX products have a narrower range of accepted values. Failed products are marked and moved aside and repaired.

The final tests are either performed by a test person or by the assembly worker, depending on the product. Tested and approved ATEX products are supplied with an ATEX label as a sign of approval.

### 3.8.7 The finished product

The finished products are packed in boxes and put on the storage shelves for finished products. ATEX product and normal products are stored on the same shelves. ATEX products are recognizable by the ATEX box label. The task list is returned to the production manager, the products are shipped and the order is closed. All work stages on the task list have been signed with the initials of the performer. Failed items are also documented here.

## 3.9 Product Tailoring

I discussed the product tailoring processes with Ville Maijala, Technical Product Manager at Savox Communications. The protocol is found as Attachment 9.

### 3.9.1 Product tailoring

The product tailoring process begins at the sales department. They receive a request from the customer and forward it to the Technical Product Manager. In case of an ATEX product, the assignment should contain the requested ATEX class and the customer's certificate of the item to which the product will be connected. Every assignment is examined by the appropriate hand and is then accepted or rejected as a tailoring project.

Approved assignments go into the design phase. This usually means changes to the hardware and the mechanics. If the tailoring project entails updating the product to ATEX, the material of the plastic parts must be changed to leading material. Additionally, circuits must be appropriately protected, as demanded by the ATEX standards.

### 3.9.2 ATEX certification

The tailored product can either get approved with a new certificate or with a supplement to an existing certificate. If the changes do not affect ATEX critical parts, the product can be approved simply by getting the revised document stamped and signed by the NB. The documents and possible proto types are sent to the Notified Body. The most important electronics documents needed for certification are: PCB layout, PCB BoM, PCB schematics and cable connection documents.

### 3.9.3 Demonstration

A demonstration project produces a single specimen for demonstration purposes to the customer. There are no product documents, only drafts. Furthermore, ATEX demonstrations product do not have to be certified. The draft documents are not made official, but remain in the product modification folder.

### 3.9.4 Process control

The tailoring and demonstration project processes are controlled with a series of action lists and document checklists created by the product tailoring responsible person. ATEX relevant phases and required documents are marked as such. These projects often have a tight timetable, so the checklists are crucial for the projects.

## 3.10 Auditing

This part was examined through first hand experience of the ATEX audit processes. Knowledge was gathered through planning and attending three audits. The first one took place on 30th June 2007 at Savox Manufacturing Services, the production unit of Savox Communications. The second audit was at the main circuit board subcontract manufacturer of Savox Communications on 31st June. The third one was on 14th September at a supplier of ATEX critical plastic parts.

The Company must audit the production unit and all ATEX critical suppliers at least once a year. The ATEX responsible person manages the ATEX audits and the necessary documentation that results from the auditing process. He must also see to that deviations found during the audit are corrected.

### 3.10.1 The purpose of an audit

The ATEX processes are examined during the audit. The purpose of the audit is to ensure that the processes fulfill the required quality norms. The Directive, the standards, the Notified Body, the Company and the customers of the Company set the requirements for the quality norms. The Company presents these to the audited agent.

### 3.10.2 Audit report

The results of the audit are documented. The audit report is then delivered to the audited agent so that the deviations and remarks can be tended to. The report contains the observed deviations as well as the person or agent responsible for managing them. The improvement actions are also documented in the audit report. The final report is filed.

## 3.11 The ATEX Responsible Person

The interviewed agent was Kai Leppälahti, ATEX responsible person at Savox Communications. The protocol can be found as Attachment 6.

### 3.11.1 ATEX classification

The customer usually decides on the ATEX class and category. The decision is based on the classification of the radios and other equipment intended to be used with the Company's products. However, for an internal project this is not the case anymore. (Internal projects can be instigated for instance by the need for products with lower production costs.) It is not defined who is responsible for choosing the ATEX class in these kinds of projects.

### 3.11.2 ATEX critical segments

The parts that have to be especially considered when designing an ATEX product are defined as the ATEX critical components. These are for example plastic casing parts and the circuit board. The ATEX criticality is pointed out in the documentation and changes can only be made with, depending on the document, the permission of the ATEX responsible or the NB. Generally the designer defines which components should be treated as ATEX critical. The ATEX responsible and the NB can also give their input regarding to this matter.

The designer performs the necessary test and calculations related to the ATEX critical components. The designer should know the standards well enough to be able to apply the right test. The ATEX responsible must know the standards well enough to be able to double-check that all the right tests have been performed.

### 3.11.3 ATEX project coordination

There is a range of different project that can be labeled as ATEX projects. These include ODM (Original design manufacturer), OEM (Original equipment manufacturer), internal, product modification and certification projects. All ATEX projects must be coordinated through the ATEX responsible person. At the moment the ATEX responsible person has also managed part of the ATEX internal projects.

## 3.12 Record Retention

All records concerning ATEX are marked as such in some way. It should always be possible to realize from the records and documents that the product or project is ATEX. The records are stored in paper or electronic form, or both. To allow traceability, all records concerning ATEX have to be retained for at least ten years. This is stated in the Directive. A table of the most relevant ATEX records is found as Attachment 10.

# 4 DISCUSSION

This section discusses and analyses the results of the interviews. The detected problems based on the results of the inquiries as well as the solutions to the problems are presented - sometimes on a theoretical level and sometimes a practical one. Furthermore, the responsible agents for solving the dilemmas are identified. The Directive and the standards have occasionally been utilized when attempting to find the solutions.

A handful of the examined processes work efficiently and it was decided that no improvements were needed. Therefore no recommended actions are suggested. The processes are merely commented.

The chapters more or less follow the same structure as in the Materials and Methods- and the Discussion-sections. The customer and the sales department are observed separately; the Record Retention-section is left out and is one new chapter called Additional. This chapter covers some extra thoughts and recommendations.

## 4.1 The Customer

### 4.1.1 Dilemmas in current system

At the moment the customers and end-users are unsure of what kind of devices safely can be interconnected. There is also a general uncertainty as to the classification structure for ATEX products, i.e. the ATEX equipment categories, classes and zones.

### 4.1.2 Recommended actions

The customer should be able to identify the experience and competence of the Company concerning design and manufacturing of ATEX products. The customer determines the market need and decides the ATEX criterion for the product. The ATEX classification should be based on the operation area and the associated apparatus.

The customer must take into consideration the atmosphere in which the product is going to be operated. According to EN IEC 60079-14, section 5, the following information is required in order to select the appropriate apparatus:

1. Classification of the hazardous area.
2. Temperature class or ignition temperature of the gas or vapor involved.

3. Where applicable, gas or vapor classification in relation to the group or subgroup of the electrical apparatus.
4. External influences and ambient temperature.

It is also the customer's responsibility to choose an appropriately classified ATEX apparatus with regard to the item it will be plugged into. Intrinsically safe devises must follow the provisions of EN IEC 60079-14, section 12. According to this section the following matters must be taken into consideration:

1. The sum of the maximum effective internal capacitance $C_i$ of each item of intrinsically safe apparatus and the cable capacitance shall not exceed the maximum value $C_o$ marked on the associated apparatus.

2. The sum of the maximum effective internal inductance $L_i$ of each item of intrinsically safe apparatus and the cable inductance shall not exceed the maximum value $L_o$ marked on the associated apparatus.

3. The values of permissible input voltage $U_i$, input current $I_i$ and input power $P_i$ of each intrinsically safe apparatus shall be greater than or equal to the values $U_o$, $I_o$ and $P_o$ respectively of the associated apparatus.

4. The maximum temperature can be determined from the values of $P_o$ of the associated apparatus to obtain the temperature class.

5. The apparatus group of the intrinsically safe circuit is the same as the most restrictive grouping of any of the items of electrical apparatus forming that circuit (for example a circuit with IIB and IIC apparatus will have a circuit grouping of IIB).

### 4.1.3 Responsibilities

To prevent the wrong equipment from being used with the improper associated apparatus in the improper area, the customers has to have knowledge about the before mentioned standard. They most also be aware of their responsibilities concerning the choosing of the ATEX class. If this information is not found within the customer's own group, it must be delivered from the Company. It is the obligation of the Company to not knowingly put on the market products that will not be used appropriately. Therefore, it is up to the sales representative to convey this message and information to the customer. Conversely, it is the customer's responsibility to follow the provisions of the before mentioned standard.

## 4.2 Sales

### 4.2.1 Dilemmas in current system

The sales persons are unsure of which products and plug-in accessories can be interconnected. There is also uncertainty when it comes to understanding the ATEX certificates and which products fall under the certificates.

### 4.2.2 Recommended actions

The sales department needs a list of the products and the product accessories - a matrix of the product portraying the different combination possibilities. The sheet would work as a map of the available products. The customer should be able to get this information immediately when needed. And there cannot be any confusion or misunderstanding as to what product combinations are available to the customer.

They should also have a list of the certificates and products under the certificates. It is important that the customer or end user gets the correct certificate at request. The range of certificates at the Company should be common knowledge amongst the sales representatives.

Furthermore, they need to be aware of the development of the projects and changes in timetables. The customer may be left uninformed of changes to the product or release date if the sales representative does not have this information.

### 4.2.3 Responsibilities

A sales representative must be familiar with the major outlines concerning the Directive. It is important to understand and recognize the ATEX classes and categories as well as the temperatures and environments suitable for products in the different classes. A sales person must have a broad enough knowledge about ATEX issues to be able to grasp new concepts put to him or her by the customer. As stated in section 3.1.3 ATEX competence, the sales person does get training before commencing his or her duties. However, if ATEX issues are new the person, it is difficult to take in all the information.

In addition, the sales department must be aware of the competence, regarding ATEX, of Company and be able to promote this to the customer. The sales person is the window to the market and the customer and he or she must give the impression that the Company is capable and competent regarding ATEX issues.

The ATEX responsible should make, or supervise the making of the necessary list of certificates, ATEX products and accessories for the sales department.

## 4.3 Project Management

### 4.3.1 Dilemmas in current system

One dispute in the project management process is the timetable versus clever design. In other words, should the product quickly be put on the market or should the designer take his time and add features for possible future purposes. This is in essence a question of strategic opinions - having long-term goals or short-term goals concerning customer satisfaction.

Another problem is the lack of a product family manager. There is nobody to manage and coordinate the different projects within the same product family. This leads to redundant work, especially when doing product modifications.

### 4.3.2 Recommended actions

There must be equilibrium between the need for tight timetables and the need for clever design. For example, if the product in question is not ATEX, but will be in the near future, it might be wise to design the circuit board so as to allow upgrading to ATEX with changes merely to the components, not to the layout or schematics.

There should be a discussion about ATEX and product family issues before the project begins, in other words before Milestone 0. The product family must be taken into consideration when planning a new product. Changes in a product will always affect the rest of the product family, not to mention the product accessories.

The ATEX classification is also important to discuss at an early state, since the class directly determines what radios and accessories can be plugged to the product. Even though the customer usually has their request for the ATEX class, it can be revised and for instance be changed to a more restrictive class. This may spare the Company the effort of updating the product later on.

As mentioned in section 3.2.2 ATEX project management, no ATEX projects have been managed with the current system. It is therefore important to monitor the management system during the first ATEX project and make necessary updates afterwards.

### 4.3.3 Responsibilities

The management and board of directors decide on the policy as well as on the product and project strategy for the Company. The project manager, the sales representative and the head of the R&D department should together decide on the tactics for implementing the sought after strategy.

The product manager and the ATEX responsible should together add the issue of the ATEX discussion as part of the project to the Project Handbook. The ATEX responsible decides what facts should be discussed and the project manager sees to that the project step fits into the whole of the project.

## 4.4 NPI

Timing is important for the NPI processes. It is crucial to provide the documentation responsible person with the assignment as early as possible. Otherwise there can be delays in the schedule. It is also important to double check that all ATEX critical components have been marked as ATEX in the lists provided to the documentation responsible. Otherwise they will be marked as normal components in the component and product register and treated as such.

## 4.5 R&D

### 4.5.1 Dilemmas in current system

One dilemma is the progression of the product development. The circuit boards, for instance, make too many loops in the designs process flow. The problems are not identified in time and the process goes back to square one. Especially ATEX products tend to circulate in the process flow.

Another problem is the documentation process. The documents are not generated during the design process, so they are not immediately available when the certification process begins. Additionally, ATEX mechanical drawings are not marked as ATEX. Finally, the expertise amongst designers concerning the technical attributes of ATEX design should be developed.

### 4.5.2 Recommended actions

The designer and project manager must remember to follow the steps set by the flowcharts and the checklist. The project should not proceed if the conditions of the milestones have not been met. This is the objective of the milestone and checklist system. Furthermore, the ATEX phases should be defined more precisely.

There must be a folder for the certification documents the under the project folder. The certification folder can have subfolders for the different element of the projects. The folder should be created before M2. The documents should be added between M3 and M4 under the supervision of the ATEX responsible. Most importantly, when the project

reaches the certification point, the documents should already be finished. When the timetables are made, the documents are expected to be finished at this point. If they are not created parallel to the designing process, the timetable will be impossible to follow.

The designers should at the end of a project go through the lessons learned during the project and share new knowledge and information with the rest of the team. This way the skills will reach out to all designers. The knowledge could, for example, be about the standards, new safety circuit implementations or test points. The developers especially need to know the standards EN IEC 60079-0, Electrical apparatus for explosive gas atmosphere - General requirements, covered in section 1.3.2 and EN IEC 60079-11, Explosive atmospheres- Equipment protection by intrinsic safety “i”, covered in section 1.3.3.

Other sources of ATEX training for the designers could perhaps be the Notified Body. The NB has vast experience of not only the technology, but also of literature and other material that could help the designers develop in this field. The NB also has contacts and could probably refer the Company to an agent that offers ATEX training.

### 4.5.3 Responsibilities

The project manager is responsible for controlling that the project follows the process course defined in the project handbook. He or she must also see too that the necessary documents are created during the project.

The ATEX responsible must make certain that there is a folder for the certification documents the under the project folder. The documents can be transferred there by the designer or by the ATEX responsible.

The R&D manager should organize the “lessons learned” occasion after the project has ended. Designers involved in ATEX projects should attend the occasion. The ATEX responsible person could also be invited.

The R&D manager and the ATEX responsible person should actively search for further ATEX training for the designers. Moreover, if somebody at the Company comes across a suitable training event, he or she can suggest that the designers attend the training.

## 4.6 Documentation

### 4.6.1 Dilemmas in the current system

There is not a consequent system for retaining the ATEX documents. Sometimes the old and new documents are mixed in the same folder. It is also difficult for other people to find the documents they need.

Another problem is that the documentation responsible does not get the needed information on time. This causes delays in the project, because the documents cannot be created due to lack of information. The same goes for the certificates and some other documents.

Changes to documents containing ATEX critical material must get the approval from the Notified Body. At the moment there is a single Bill of Material for the PCBs. The BoM lists both ATEX critical and normal components. Consequently, changes to non-critical PCB components also require approval from the NB.

### 4.6.2 Recommended actions

The document system should be structured so that everyone can find what he or she needs to. The documents should be accessible to everybody. The documents must be retained with a logical and continuous system. ANNEX IV of the Directive states that the ATEX related records should be documented in a systematic and orderly manner.

The documentation responsible must receive the ATEX details, certificate information and the product information as soon as it is available. This information is crucial for the creation of the production documents. The faster the information is delivered, the sooner can the documents be created, approved and utilized.

For instance the PCB part list could be split into two documents, one with ATEX critical components and the other with normal components. Subsequently, only changes to ATEX critical components would require a change to the certificate. Changes directed at non-critical components would not need approval from the NB.

### 4.6.3 Responsibilities

The documentation and the ATEX responsible persons should take charge in constructing the ATEX document system so it serves the needs of everybody who needs the documents. It is important that the documents are easily accessible.

It is the responsibility of everybody involved in the documentation process of a project to deliver the necessary information to the documentation responsible. For instance, the NPI manager and the product tailoring responsible must deliver the ATEX information in the beginning of the project. The ATEX responsible must return the scheduled and related ATEX documents to the documentation responsible as soon as they are approved. Only then can one be sure that the correct documents are ready on time.

The ATEX responsible and the R&D manager should discuss whether splitting the part list into a critical and a non-critical part is convenient. The HW designers and the NB may also have relevant input in the discussion.

## 4.7 Sourcing

### 4.7.1 Dilemmas in the current system

Some suppliers have not manufactured ATEX critical material prior to supplying the Company with such material. Consequently, a number of suppliers do not understand the high quality standards required of them as ATEX critical suppliers and they are not familiar with the provisions of the Directive and the standards.

### 4.7.2 Recommended actions

The supplier evaluation should deal with the question of what the supplier knows about ATEX issues. This provides the Company with an important factor for comparison between suppliers. The more previous knowledge about ATEX a new supplier has, the less training will be necessary. Hence, new suppliers should preferably be familiar with the Directive and the provisions it sets on suppliers of ATEX critical material. The sourcing manager is naturally responsible for updating the supplier evaluation checklist

## 4.8 Suppliers

### 4.8.1 Dilemmas in the current system

Sometimes the supplier does not understand the need for the quality requirements. This could be due to the fact that few of the supplier's customers need the same degree of quality the Company requires. Therefore the supplier is opposed to implementing the extra quality measures, for instance batch tracking.

The suppliers do not always wish to follow the actions recommended by the Company although it clearly would increase the product yield of the manufacturing. They either do not believe the actions will improve the yield or they do not know how to implement the recommended actions.

### 4.8.2 Recommended actions

The suppliers providing ATEX critical material for the Company must understand the high expectations set on them. Only then can they be expected to rise to the level of quality that the Company demands. The suppliers must receive training concerning the Directive, the standards and the internal standards of the Company. The Company must also give exact instructions for testing, marking procedures.

The suppliers need to follow the advice of the quality manager. Especially in the cases when the quality manager of the Company turns out to be more experienced with process control than that of the supplier's quality manager. Otherwise will the level of quality not improve and rise to the required level.

### 4.8.3 Responsibilities

The quality manager and the ATEX responsible person must emphasize the importance of the quality standards and remind the supplier that the customer is always right. They must also train the suppliers when it is required. Experts from the production unit of the Company can have valuable input concerning the training.

## 4.9 Production

The production unit on the whole works well. The ATEX processes are identified and defined. The ATEX parts and products are marked and distinguished throughout the production process. The parts and product are checked and tested according to the Directive and standard. The problems and deficiencies are identified and effectively dealt with. The management is willing and driven to constantly improve the processes. The staff is trained and aware of its responsibility.

## 4.10 Product Tailoring

### 4.10.1 Dilemmas in the current system

At times the tailoring projects do not follow the set timetable. This is often due to the lack of information from the customer. The information can be radio output details, ATEX classification or other information from the radio certificate that is vital for the project. It is also unclear as to who is the responsible agent for requesting the information from the customer.

### 4.10.2 Recommended actions

As mentioned in section 3.9.4 Process control, the tailoring process is controlled with a series of to-do lists. There it is defined what information must be available before beginning the tailoring project. The persons responsible for performing the task are also defined in the checklists. It is important to follow the checklists and get the necessary information on time.

### 4.10.3 Responsibilities

The sales representative and the tailoring responsible person must see to that the tailoring process follows the product customization checklist. If needed, the ATEX responsible person can be consulted in ATEX projects. In practice, the tailoring responsible person must also have an understanding of ATEX issues.

## 4.11 Auditing

### 4.11.1 Dilemmas in the current system

The ATEX audits and the deviations discovered during the audit are not always followed up afterwards. The deviations are discussed during the audit, but the improvement action is not performed. This defeats the whole purpose of the audit.

Some deviations might slip by the auditor because he takes the word of the audited person instead of actually checking the item itself. It does not mean that the person is trying to deceive the auditor; he might be as unaware of the problem as the auditor. The main point is that the deviations are brought into light so they can be addressed.

### 4.11.2 Recommended actions

The deviations are recorded in the audit report. The recommended action can also be documented, as well as the person or persons responsible for performing or managing the recommended action. Completed actions are signed for and the audit is not closed before all deviations have been deal with. Otherwise the auditor will probably find that the same problems still exist at the time of the next audit. It is simply not enough to name the problems, they must active be solved.

Instead of just discussing about with the audited issues, the auditor should demand to see them work in practice. For example, a complicated system like batch tracking might work in theory, but the system might be deficient in reality. To discover if the system works, one must actually backtrack a part or product and see if it is possible to discover its origin (batch, purchase date, etc.).

### 4.11.3 Responsibilities

The ATEX responsible person manages the ATEX audits and audit follow-ups. The quality manager can be consulted if necessary. The agent responsible for dealing with the deviations is mentioned in the audit report. This agent must either resolve the problems himself or see to that somebody else solves them.

## 4.12 The ATEX Responsible Person

### 4.12.1 Dilemmas in the current system

Occasionally ATEX details get sidestepped in the project because the ATEX responsible or some other ATEX expert has not been involved in the project from an early point. There is nobody in the team to promote the ATEX issues and important detail can be bypassed.

The projects are handled from case to case and are not seen as parts of a bigger picture. For example, an ATEX tailoring solution can be almost the same as for another ongoing ATEX project. The tailored and the other product could possibly be realized with the one and same solution, saving time and resources.

It is impossible to make a project timetable because the certification process is impossible to predict. This goes hand in hand with the fact that the time and staff resources at the NB are not monitored or taken into consideration. The Company presumes that the NB will have time for their project from the moment the project is delivered to them.

### 4.12.2 Recommended actions

The ATEX responsible should take part in the ATEX projects from M1 when the technical specification is created. He will then have a good perception of the project when the time comes for making decisions concerning ATEX details.

There should be an overview of all the ATEX projects. Only then would it be possible to realize when different ATEX project overlap. The ATEX responsible person should have a general idea of all the ongoing ATEX projects. If he notices similarities between different projects, he can hint this to the project managers. Especially if there is not a product family manager, the input of the ATEX responsible is important.

The ATEX responsible should organize the schedule at the NB. He should also prioritize the projects that are to be certified. The ATEX responsible person should discuss these matters with the NB. There must be a mutually degreed upon strategy with the NB concerning timetables and project schedule allocations.

### 4.12.3 Responsibilities

The ATEX responsible person should be seen as a consultant concerning ATEX issues. He supervises the ATEX processes and counsels the persons performing the tasks. He is also responsible for performing the tasks associated with the NB and quality issues, such as certification and auditing.

## 4.13 Additional

### 4.13.1 Training

The ATEX responsible person trains new employees with relevant ATEX issues. He or she should also arrange further training when necessary. The training could be for the whole company or on department level. The training on department level should include integration of ATEX processes into the process flow. The head of the department should give his or her input concerning the training material.

### 4.13.2 ATEX flowcharts and schemes

The ATEX processes need to be defined and charted with flowcharts. This will allow the team to get an overview of the ATEX process steps and at the same time the areas of responsibility will be defined. The ATEX responsible must cooperate with the departments to develop the system that will enable the certification process to flow seamlessly.

The ATEX responsible supervises each step of the process to ensure that everything is carried out according to the provisions of the Directive and the relevant standards. This will also ensure that all necessary information is at hand when the product is ready to be certified.

### 4.13.3 Consistency and completeness

The process checklists and milestones have been created to help ensure consistency and completeness in carrying out a project. If the milestone reviews are not afforded the right amount of time and energy, they stop having a useful function. Each action in the process has to be carried out with regard to the upcoming actions. Mistakes and shortcuts tend to have a negative impact on the following process steps. Instead of deeming the process too time consuming and then making shortcuts, the person should evaluate the checklist and consider revising that.

### 4.13.4 Communication and teamwork

The key to a successful process flow is teamwork between the departments. It is not enough that the segments work independently. The information and knowledge must travel between the interfaces. Otherwise the working segments are of no use. The process moves forward for a while but gets stuck on the verge of the next step. Information must be shared openly and one can never assume that one’s colleague holds the same information as oneself.

### 4.13.5 ATEX frame of mind

The Notified Body certifies the products of the Company. However, it is the responsibility of the Company to ensure that the NB has the means to carry out the certification process. This means developing the quality processes of the Company and delivering the complete information package within the schedule.

To be able to achieve this objective, the Company must focus on ATEX issues on a strategic level. The ATEX responsible and the Company must emphasize how important it is to take ATEX issues into consideration at every step of the project process. ATEX issues must be given attention even when developing normal products. In fact, ATEX products should be seen as the norm and normal products as exceptions to the norm.

# 5 CONCLUSION

This chapter concludes and analyses the success of the study. Furthermore, a few other certification organizations similar to ATEX are presented. The purpose of the study was to determine whether the ATEX processes of the Company match the stipulations set by the Directive. In addition, suggestions for improving the ATEX processes leading to the certification of the products of the Company were presented. Lastly, the responsible agents for the recommended actions were named.

## 5.1 The study

### 5.1.1 The Interviews and Identifying the Problems

The purpose of the interviews was to get a solid foundation of information of the processes of Savox Communications. Based on this information the problems in the processes were determined. This procedure turned out to have a great outcome. Not only did the problems surface during the course, it also created discussions and a more open attitude towards problematic ATEX issues. The discussions transformed the obstacles into challenges; challenges to be solved.

### 5.1.2 Solutions to the Problems

The problems were not only identified, but recommended solutions were found and to a satisfactory level. As expected, the solutions were often within the minds of the employees. Discussing the matters openly allowed the solutions to be extracted. By interacting with the employees and being involved in the processes, the needed information was found. Information from the Directive and the standards were also relied upon when needed. Furthermore, the responsible agent in each case was successfully determined. This is the person or persons that will manage the process of implementing the suggested solutions. The ATEX responsible person can also be consulted in all ATEX issues.

### 5.1.3 Solving the Problems

The next step is to implement the recommended solution and solve the problems in practice. This is going to happen through, among other things, training of the staff and updating the quality system, process descriptions and other instructions. The source for the training material will be this thesis. The departments or persons will be separately trained on issues important for each department. The staff will also be able to present

their own questions and insecurities concerning ATEX issues. The ATEX quality system, descriptions and instructions will be updated over the following months. The updating process will be led by the responsible persons determined in this study, as well as by the ATEX responsible person. These issues will also be taught to the staff as soon as they have been updated.

## 5.2 Other Certificates

A drawback with ATEX is that it only applies for European countries. The rest of the world uses other certification standards. However, ATEX does open the door for other certificates. By using the skills acquired during the development of ATEX products, one can more easily expand the market by getting the product certified with other standards. Other certification organizations include IECEx, FM, UL and CSA. Next follows a short description of these.

### 5.2.1 IECEx

IECEx stands for the Intenational Electrotechnical Commission Scheme for Certification to Standards Relating to Equipment for use in Explosive Atmospheres (IECEx Scheme for short). This certification organization is quite similar to the ATEX system. The major difference is that while ATEX is a European system, IECEx applies to different countries worldwide. The standards are the same for IECEx and ATEX and the quality audits can be performed on the same visit. In other words, certifying ATEX products for the IECEx market is quite straightforward.

### 5.2.2 UL

UL stands for Underwriters Laboratories and is a U.S., privately owned company established in 1894. UL is a product testing and certification organization that develops standards and test procedures for products. UL also test and approves equipment intended for use in hazardous locations. Approved products are marked with the UL logo. The hazardous areas are divided into classes, divisions and zones and by that do not correspond to the ATEX classes and zones.

The relevant standards are:

- UL 913, Intrinsically Safe Apparatus and Associated Apparatus for Use in Class I, II, and III, Division 1, Hazardous (Classified) Locations and

- UL 2279, Electrical Equipment for Use in Class I, Zone 0, 1 and 2 Hazardous (Classified) Locations

### 5.2.3 FM

Factory Mutual, FM Approvals develops product safety standards. FM Approvals also tests and certifies products of companies worldwide. When a product meets FM Approvals' standards, it is issued the FM APPROVED mark to signify it will perform as expected. The hazardous areas are divided into classes, divisions and zones and by that do not correspond to the ATEX classes and zones.

Relevant standards are:

- FM 3600, Electrical Equipment for Use In Hazardous (Classified) Locations - General Requirements

- FM 3610, Intrinsically Safe Apparatus and Associated Apparatus for Use in Class I, II, and III, Division 1, Hazardous (Classified) Locations

### 5.2.4 Implementation

Although the above-mentioned certification systems vary from the ATEX certification organization, experience with ATEX will take you a long way. Since many of the tests required for certification are the same these organizations, the cleverest thing would be to find a certification agent that can perform the ATEX as well as the above-mentioned certifications at once. This would save time and resources for the Company, since similar tests do not have to be performed twice.

# 6 REFERENCES

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ATTACHMENT 1

Interview by Linda Ehnholm with Mikael Westerlund, head of sales department at Savox Communications Oy Ab, 11.05.2007.

Question:
What does a sales person have to know about ATEX to be able to sell an ATEX product?
Answer:
The basics of the Directive and product classes and categories and in what environments the products can be operated.

Q:
Who is responsible for the ATEX training of the sales persons?
A:
The ATEX responsible person.

Q:
What is different in the sales process if the product in question is ATEX?
A:
Nothing is different. The sales process is the same for normal and ATEX products.

Q:
Are there any additional sales documents or records if the product in question is ATEX?
A:
No, the records and documents are the same for normal and ATEX products.

Q:
Where are the sales processes described?
A:
In the Operation Manual

Q:
Does the ATEX responsible have to be consulted when the business case is made?
A:
No

Q:
Who provides the necessary information for the product specification?
A:
The customer

___/___2007, Espoo

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Mikael Westerlund Linda Ehnholm

ATTACHMENT 2

Interview by Linda Ehnholm with Antti Ranta-aho, Project Manager at Savox Communications Oy Ab, 14.08.2007.

Question:
Tell me about the process of making the project timetable and how you take the certification process into account.

Answer:
The preliminary timetable is made in connection with the business case, before M0. It is then revised in the technical specification phase, before M1. If required, updates can be made after this. I map out the workload of the project and determine resources needed to finish the project. This produces the schedule.

No ATEX projects have to this date been managed with this project management system, so I do not have any experience with that. There should be a system with which we would be able to determine more precisely how long the certification will take and what documents and materials are required for certification.

Q:
What is important when managing a project?
A:
It is important to follow the schedule and get the projects finished as soon as possible. This keeps the customers satisfied. And I always try to emphasize how important it is to focus on this project, not on what changes might be made to the product in the future. If it is not an ATEX product, do not waste time designing it like one, just because it might be changed to ATEX in the future.

Q:
Is there something missing in the business cases or product specifications as they are made now?
A:
The product lifecycle is missing.

___/___2007, Espoo

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Antti Ranta-aho Linda Ehnholm

ATTACHMENT 3

Interview by Linda Ehnholm with Patrick Söderbäck, NPI manager at Savox Communications Oy Ab, 28.08.2007.

Question:
Do you provide the documentation responsible person with the part numbers for a new product?

Answer:
Yes. I compose a list with all the part numbers. The ATEX critical parts are marked with ATEX. I am the only one permitted to revise the list. When the part or the information about the part changes, I update the list.

Q:
How do you ensure that all the critical ATEX components in the list are marked as such?
A:
I review the list at least with the ATEX responsible before approving it.

Q:
How do ensure that all the necessary production documents are prepared?
A:
I provide the documentation responsible person with a list of the documents that have to be created. Document checklists help me manage this.

Q:
What ATEX issues do you have to deal with?
A:
I see to that the necessary ATEX related markings, labels and documents are created. I also see to that the ATEX responsible gets the necessary proto types for testing and certification purposes.

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Patrick Söderbäck Linda Ehnholm

ATTACHMENT 4

Interview by Linda Ehnholm with Mikko Hellström, R&D Manager at Savox Communications Oy Ab, 23.05.2007.

Question:
What is a product specification?

Answer:
It is a document prepared before milestone M0, by a team usually consisting of the project manager, a sales representative, the R&D manager and the engineers. The ATEX responsible person is informed of the new ATEX project, but is otherwise not involved at this point. The document specifies the functional blocks of the product, including the ATEX safety functions. The document can also contain "lessons learned" from previous projects in order to avoid repeating prior mistakes.

Q:
What is a technical specification?

A:
It is a document prepared before milestone M1 by engineer(s). The document specifies how the functional blocks are to be realized. This includes the ATEX product class and category (sometimes already provided by the customer), temperature and IP class. Furthermore, when the ATEX requirements are known, one can list the standards that apply for the product. The ATEX responsible person takes part in approving the ATEX product class.

Q:
What is the next step in the process?

A:
Before M2 the HW engineer designs the circuits and confirms, by calculating, that the parameters apply with the standards. The designer lists the tests that need to be performed on the prototype. These include measuring the diodes, checking the insulation space, measuring the surface temperature (taking into account the ambient temperature), checking the insulation of the radio cable and checking the connector at the radio end. In other words, the safety elements associated with the ATEX standards are examined. When the layout and the part list are finished a prototype(s) is made and the test are executed. (Only functional tests are performed on a non-ATEX product). The outcome of these measures includes the following documents: PCB schematic, BoM, specification, info of labeling, coating, screen print and layout. In addition, a preliminary version of the safety declaration and battery test report.

The mechanical engineer must remember to use anti-static material for the plastic parts.

Q:
What happens between M2 and M3?

A:
At this point the safety declaration must be finished and the ATEX critical components marked in the BoM. The ATEX and environmental test units are available and the tests are performed. If the product is new, the environmental tests are done before the product is sent to VTT, but in some cases the tests can be performed simultaneously. IP test will also done at this point; it is being implemented at the moment.

Q:
What happens between M3 and M4?

A:
The product is ascertained to meet the standards of the specifications and the test reports are finished. The HW engineer designs the (ATEX) PCB testing specifications for production. The ATEX responsible files the ATEX application and composes the ATEX safety guide.

Q:
What happens between M4 and M5?

A:
The ATEX certificate is granted. After M5 the product is in production.

Q:
What are the major concerns regarding ATEX?

A:
- The know-how concerning safety circuit connections. There might be a better and simpler way of implementing this attribute.
- The sound level is poor in ATEX products because the signal level has to be limited and there is not enough space for the speakers to work properly.
- It would be good if the HW engineers could get some training to improve their technical knowledge concerning ATEX products. I have tried but not found a place where to get this kind of training.
- The certification process with VTT is too slow. Either this process has to be improved or we should think about getting the products certified somewhere else.

___/___2007, Espoo

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Mikko Hellström Linda Ehnholm

ATTACHMENT 5

Interview by Linda Ehnholm with Ilse Saarinen, Technical assistant at Savox Communications Oy Ab, 28.06.2007.

Question:
How does the documentation process start for you?
Answer:
I usually receive a new part number request from Ville and start working on it from there. The request can either be for a part or a whole product. If it is an ATEX part, it is noted in the document. If it is a product, the ATEX classification must also be noted. I feed the new part number(s) into Scala and the product document management system. If the case in question is a whole product, I also feed the product number. Scala has a separate template for ATEX products/parts, which by default marks the product/part as ATEX. The document management system also has templates for product families, also separately for ATEX products.

Q:
Then you start preparing the documents?
A:
Yes. I put together the necessary documents under the folder Product documentation. Then all documents have to be approved by the right persons. Scheduled and related drawings that need approval from the notified body or the ATEX responsible are delivered to the ATEX responsible person.

When the documents are approved, I put them in the folder Part trap in pdf format. Sometimes there are delays because I don't get the approved document straight away. The same goes for the certificates and some other documents. I also need the ATEX classes as soon as possible, to be able to create the documents.

Q:
What happens when the documents are approved?
A: Hena feeds the product construction into Scala, under the product number. After this the product is ready for production.

Q:
What extra documents does an ATEX product have?
A:
Epoxy casting description, epoxy instructions, ATEX safety guide, ATEX product label instruction, ATEX box label instruction.

___/___2007, Espoo

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Ilse Saarinen Linda Ehnholm

ATTACHMENT 6

Interview by Linda Ehnholm with Kai Leppälahti, Sourcing manager and ATEX responsible person at Savox Communications Oy Ab, 27.08.2007.

Question:
In the case of an internal ATEX project, who decides what the ATEX classification should be?
Answer:
Usually the class is chosen in line with the customer's wishes or according to the customer's radio. In other cases it is not defined who chooses the class.

Q:
Who defines which parts of an ATEX product are ATEX critical?
A:
Generally the designer, but with input from the NB and me, as the ATEX responsible.

Q:
How can the ATEX responsible be certain that all the necessary measurements, tests and calculations have been performed?
A:
The designer should know the requirements. The ATEX resp. must know the standards well enough to be able to double-check that everything crucial has been done.

Q:
How are the different ATEX projects coordinated at the moment?
A:
All ATEX project go through me, for instance product modification projects.

Q:
How does the customer know that it is forbidden for them to repair broken ATEX equipment?
A:
Check the manual. If it is not mentioned there, it should be in the safety guide.

Q:
Tell me about the evaluation process of a new supplier.
A:
I mainly check their quality system. If they do not have a quality certificate, I have to check that their processes are under control. The supplier also receives ATEX training from me.
___/___2007, Espoo

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Kai Leppälahti Linda Ehnholm

ATTACHMENT 7

Interview by Linda Ehnholm with Kimmo Turtiainen, Production Manager at Darekon-Electro Ky, 31.05.2007.

Question:
What happens to the incoming purchased material?
Answer:
The recipient checks that the packing list corresponds to the order and that the received material corresponds to the packing list. ATEX critical material is measured, if possible (one component per reel). For instance, one capacitor is measured per reel and compared to the datasheet. Approved material is provided with a sticker for tracking and ATEX critical material also with ATEX sticker. The material is placed in storage; ATEX material separately in an ATEX marked location. This system allows every component to be backtracked to which batch it came from.

Q:
What happens after you receive an order from SMS?
A:
The order is fed into the production program and the database produces a work card with the different work stages listed. After this we can put together a material list based on the part list that we have received from Savox. Savox sends us new part lists when they are updated. The material list is used to collect the components from the storage shelves. SMD and through-hole component are collected separately. The collected ATEX components are additionally checked to confirm that they correspond to the material list.

Q:
How do you manage the production stages?
A:
The production workers log every completed work stage. This way the person, task and time it is recorded. There are several visual inspections during the production process. The visual inspection of ATEX critical components takes place after the SMD loading. The PBCs are marked with an individual number. Defective items are documented and the report is sent to Savox afterwards.
All finished products are inspected in some way. The most important products, including ATEX products, undergo electrical tests. The ATEX critical components (not capacitors) are measured. The tolerances of the components determine the approval limits. The test results are automatically saved in a computer file. Failed test results are automatically routed to a separate file. Failed products are provided with a “Reject” sticker. When the circuit board changes, the test engineer is informed and he makes the necessary changes to the testing equipment. The results are sent to Savox.
___/___2007, Savonranta

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Kimmo Turtiainen Linda Ehnholm

ATTACHMENT 8

Interview by Linda Ehnholm with Jari Makkonen, Production Manager and Kirsi Sairanen, Production Assistant at Savox Manufactring Services Oy Ab (SMS), 30.05.2007.

Question:
How does the product manufacturing process begin?
Answer, Jari:
SMS receives the shipment order from Savox Communications by e-mail. We check the material and staff resources and calculate the delivery date according to that data. We print a material and task list (TT). The missing material is ordered.

Q:
Can you explain the purchase process of ATEX components?
A, Kirsi:
The component register (Scala) has all ATEX component marked with ATEX. The purchase order is also marked with ATEX. The supplier marks the packing list (lähete) with ATEX; SMS sends the packing list to Savox Com. The received material is inspected according to the specified requirements. The ATEX requirements are separately listed on the form. Batches with batch tracking are supplied with a traceability number code.

ATEX requirements in inspection
Circuit boards: Check that the boards are marked with an Ex-label + initials that indicate that the board has undergone necessary tests.
Plastic parts: Check that the parts are marked as ATEX (blue sticker + number of person responsible for testing the part at supplier). Also check the material certificate that comes with every batch. This certificate is documented with the inspection form in a folder at SMS.
Finished device: Check the test certificate of the product.
Epoxy: Material data sheet is sent once.
Neoprene epoxy cast frame: Check type, part number and revision.
Other components: Check that the product and the packing list match.

Approved ATEX parts are stored on a separate ATEX shelf. The location is found in the component register.

Q:
What about the epoxy casting of the ATEX circuit boards?
A, Jari:
The casting is usually done after the incoming inspection. The casting description is part of the production documents. The caster visually checks that there is enough epoxy and that there are not air bubbles too close to the components. The boards must be

checked and approved by somebody other than the caster. Failed boards are supplied with a ”nonstandard product”-label and reported to the production manager.

Q:
What happens next?
A, Jari:
The task supervisor prints the production documents from the document management system (Part Trap). Fresh documents are printed every time to guarantee revision control. The collector collects the components according to the TT. If the component is batch tracked, the collector compares the batch number on the shelf with the number in the register. While collecting other components, the collector always picks components from the newest batch to maintain FIFO. Semi-manufactured ATEX articles are located on ATEX marked shelves. The label responsible prints the serial number and ATEX labels on request by the collector. The serial number is found on the TT.

The collected product components are placed on separate shelves; ATEX product components on ATEX marked shelves.

Q:
Tell me about the assembly and testing process.
A, Jari:
The assembly worker visually checks that the item is correctly assembled. When the item is assembled, the worker applies the serial number label. All items undergo final testing. ATEX and non-ATEX product virtually undergo the same tests, but ATEX products have a narrower range of accepted values. Failed products are moved aside and repaired.

The final tests are either performed by a test person or by the assembly worker. Approved ATEX products are supplied with an ATEX label.

Q:
What happens with the finished product?
A, Jari:
The products are packed and put on the finished products shelves. ATEX products are recognizable by the ATEX box label. The task list is returned to the production manager and the order is closed. All work stages on the task list have been signed with the initials of the performer. Failed items are also documented here.

___/___2007, Savonlinna

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|---|---|---|
| _____ | _____ | _____ |
| Jari Makkonen | Kirsi Sairanen | Linda Ehnholm |

ATTACHMENT 9

Interview by Linda Ehnholm with Ville Maijala, Technical Product Manager at Savox Communications Oy Ab, 15.08.2007.

Question:
How does the product modification process begin?
Answer:
I receive an assignment from the sales department. The assignment is either a product modification or a demonstration. If the product in question is ATEX, the assignment includes an ATEX definition, i.e. ATEX classification and the customer's certificate. Every Friday I go through the new assignments with the head of the Operations department. He is responsible for approving the assignments.

Q:
What happens with the approved assignments?
A:
The mechanical and electrical parts of the products are designed. For an ATEX product this means the plastic casing must be leading. The ATEX documents for the electronics are: PCB layout, PCB BoM, PCB schematics and cable connection documents. Then the necessary parts are sourced.

Q:
How does the certification process go?
A:
It the same process as for a new product. The documents needed for certification are sent to the Notified Body and they certify the product. The rest of the product modification process basically follows the normal project process flow.

Q:
How does the process differ in the case of a demonstration?
A:
It is just one specimen demonstrated to the customer. There are no product documents, only drafts, and no certificate. The draft documents remain in the product modification folder.

Q:
How is this process controlled?
A:
With a checklist that contains all the necessary steps and documents. The ATEX relevant steps and documents are marked as such.
___/___2007, Espoo

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Ville Maijala Linda Ehnholm

ATTACHMENT 10

Table of ATEX records

| ATEX records | Manager |
|---|---|
| **Sales** | |
| The sales documents are the same for ATEX and non-ATEX products. | |
| **Purchasing** | |
| Supplier assessment (sourcing) | PM |
| Inspection protocol of received goods | PM |
| **R&D** | |
| PCB layout | R&D |
| PCB BoM | R&D |
| Schematics | R&D |
| Cable connections | R&D |
| **Certification** | |
| Documents for certification | AR |
| ATEX certificates | AR |
| List of certificates | AR |
| **Production** | |
| Calibration data | PM |
| Epoxy casting description | PM |
| Epoxy instructions | PM |
| Safety guide | AR |
| ATEX product label | AR |
| ATEX box label | AR |
| Component testing | AR |
| Final check and testing | AR |
| **Delivery** | |
| Delivery information (customer, date, quantity, serial number) | PM |
| Batch tracking | PM |
| **Others** | |
| ATEX training material | AR |
| Record of ATEX training | AR |
| Supplier auditing | AR |
| Internal auditing | AR |

AR ATEX responsible person
Tde Testing engineer
PM Production Manager