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A Schaeffler Company

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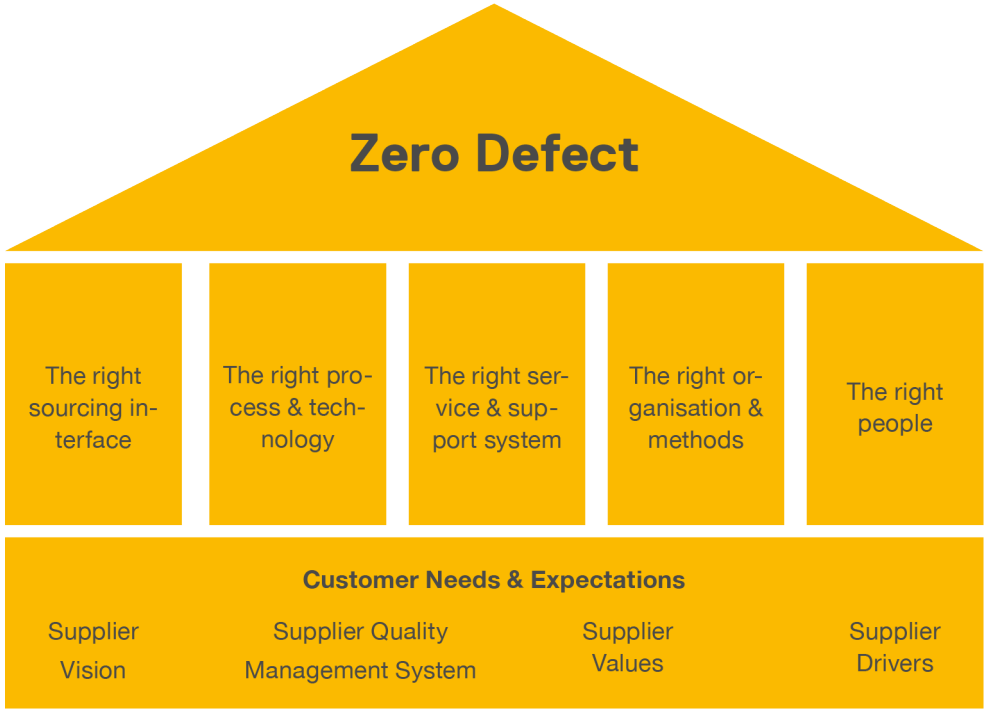
Ewellix Zero Defect

For Suppliers

"Somewhere in this world there is a company who can get SMT products and services with no problems in them. We sure would like that company to be yours …"

Philip B. Crosby



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Ewellix Group Quality Policy

Ewellix shall only market products, services and solutions that will ensure customer satisfaction by:

- Operating capable, reliable and efficient business processes
- Applying continuous improvement throughout the organization, with the objective of zero defects

Daniel Westberg

Daniel Westberg
President and CEO

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Introduction

Foreword

To grow or even sustain the business in today's extremely competitive market is to continuously produce and deliver fault free products, i.e. those containing Zero Defects (ZD).

To achieve ZD in manufacturing, you must have:

- the right sourcing interfaces
- the right process and technology
- the right service and support systems
- the right organisation and methods
- the right people

The continuous strive to achieve ZD in production is based on the following assumption: **That by fulfilling the requirements in these five areas, no defect is produced and as a result no Non-Conformance Complaints (NCC) are received or generated**.

In theory, this is the description of an ideal state. In reality, we are constantly confronted with different kinds of disturbances that dramatically increase the risk of creating a defect (or a defect escaping) in manufactured products.

The Zero Defect handbook

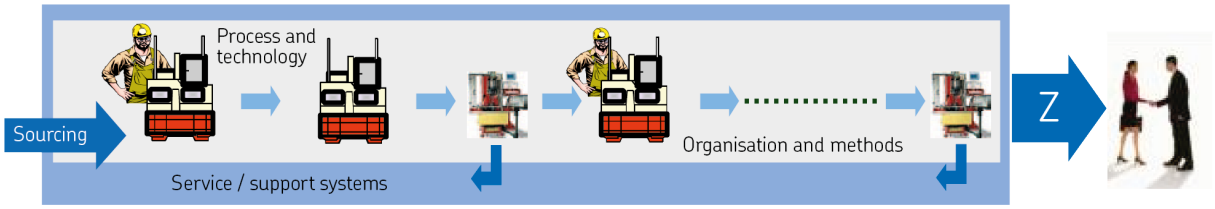
This handbook is divided into seven chapters and all these contribute to explain how a journey into ZD should look like. The five pillars of the house each deserve a special mention as they are the cornerstones to building a system whereby quality becomes the fabric of the organisation, rather than a part of the fabric. The journey towards ZD is a continual cycle of observing defects, determining their cause and then permanently eliminating that cause.

The right sourcing interface shall ensure the quality of purchased components, products, or materials are in line with the ZD approach at the interface between manufacturing and external or internal suppliers. You must understand your supplier's processes and quality procedures so that you are able to support them with appropriate methods like APQP+, ZD Audit, PPAP/FAI/ISIR and help them to both understand and meet your requirements.

The right process and technology emphasises the requirements and methods for accomplishing key activities such as process improvements, mistake/error proofing, preventive maintenance, tooling management, and problem solving processes.

The right service and support systems focuses us on all support functions in our manufacturing channels and cells, such as supply chain, the channel organisation, quality service involvement, necessary tools and approaches that are defined to run the channel in a proper ZD way. This means clear work instructions and understanding from the channel operators what these mean and how to respect them.

Zero Defect process



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The right organisation and methods focuses on the organisation, structure, and management that drive the manufacturing process. You must ensure that management is seen to be setting the requirements and ensuring they are clearly understood by the channel team, before reinforcing the ZD concept and consistently applying it.

The right people reinforce your commitment to retraining and developing personnel. It is essential that you have well-trained people that can help prevent defects rather than install new devices or processes.

Two routes towards ZD in manufacturing

The preferred route towards ZD is to eliminate all the possible sources where a defect can occur. This would involve safeguarding the machine or process itself so that neither can produce a defect. This could be accomplished by the introduction of a suitable poka yoke device to physically prevent a defect entering or escaping from the process.

The secondary route towards ZD is (at least in the short term) the limitation of the negative effects that a disturbance can have on the output. This could be the introduction of a 100% visual inspection device into the manufacturing process.

The Ewellix ZD audit tool will calculate the current risk profile for a manufacturing channel based on the 5 requirements mentioned earlier (the right sourcing interface, process and technology, service and support systems, organisation and methods, and people). This can then be used to predict and initiate actions to help prevent the occurrence of defects.

This Ewellix Group Zero Defect handbook aims to help taking the next step in the journey towards defect free production in manufacturing.

To evaluate and measure the effectiveness of the ZD processes, an audit has been developed to ascertain the current level of risk in terms of the channels' ability to function in an error free mode. This audit is called the Zero Defect Risk Assessment; an overview is given later in this handbook. This assessment is highly beneficial for the implementation of actions that aid in the rapid progression of a channel towards a stable state of ZD.

Structure and overview

The Ewellix approach

ZD implementation demands prioritisation, ability, skill, competency and enthusiasm to undertake a journey based on the five pillars from the house. These are essential ingredients if the goal of ZD is to be achieved. The Ewellix Group Zero Defect approach is built on the concepts of the Ewellix vision, Ewellix values and drivers, Ewellix customer needs and expectations, and the Ewellix Quality Management System

Model of Zero Defect at Ewellix

The figure below illustrates the ZD concept at Ewellix more fully. Each of the five pillars is shown in terms of how they are measured (Key Performance Indicators or KPI) and the key elements that go towards making up that area of work.

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ZERO DEFECT OBJECTIVE

The right sourcing interface

KPI
- Supplier NCC, supperf
- Supplier Cp / Cpk
- Supplier QCDIM
- ZD suppliers & supplied channels
- ZD awards for suppliers

Key elements
- Supplier APQP, DfSS, DFMEA
- Agreement on drawings and specifications
- Identification of critical parameters
- Capability of critical parameters
- PPAP / ISIR / FAI
- Definition of supplier process routes
- Handling of complaints
- Supplier performances follow-up
- Approval of manufacturing tools
- Purchasing & quality agreements
- Supply of ZD plan
- ZD audit, QT3 audit, CSQA audit

The right process and technology

KPI
- Cp / Cpk, LSSA
- Product audit
- NCC

Key elements
- Green flow
- SWC
- Machine reliability
- Process capabilities
- Measurement equipment reliability
- Measurement systems analysis (MSA)
- 100% inspection plan / poka yoke
- Ergonomic workplace
- Cleanliness
- Tool management

The right service and support systems

KPI
- SLR
- Control plan
- Reports

Key elements
- Handling of scrap
- Handling of rework
- Transport systems & buffers
- Identification of material
- Specific requirements
- Calibration
- Resetting
- Secured breakdowns
- Hidden factor analysis
- FIFO
- Process FMEA
- Continuous improvement
- Event logbook

The right organisation methods

KPI
- Audit result (internal and external)
- Business plan
- Control plan
- APQP+ documentation

Key elements
- External transports (including packaging)
- Product & process specifications
- Prevention of reoccurrence
- Replication of improvements
- Communication of goals & results
- Cost of non-quality
- Channel leadership & responsibilities
- TPM / ODR
- Model control plan

The right people

KPI
- Competency mapping
- Leadership review
- Training plan, WCA

Key elements
- Competence in job
- Communication between channel & operators
- ZD understanding & mentality
- Quality system knowledge

ZERO DEFECT RISK ANALYSIS AND IMPROVEMENT PLANS

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ZERO DEFECT FACTORY

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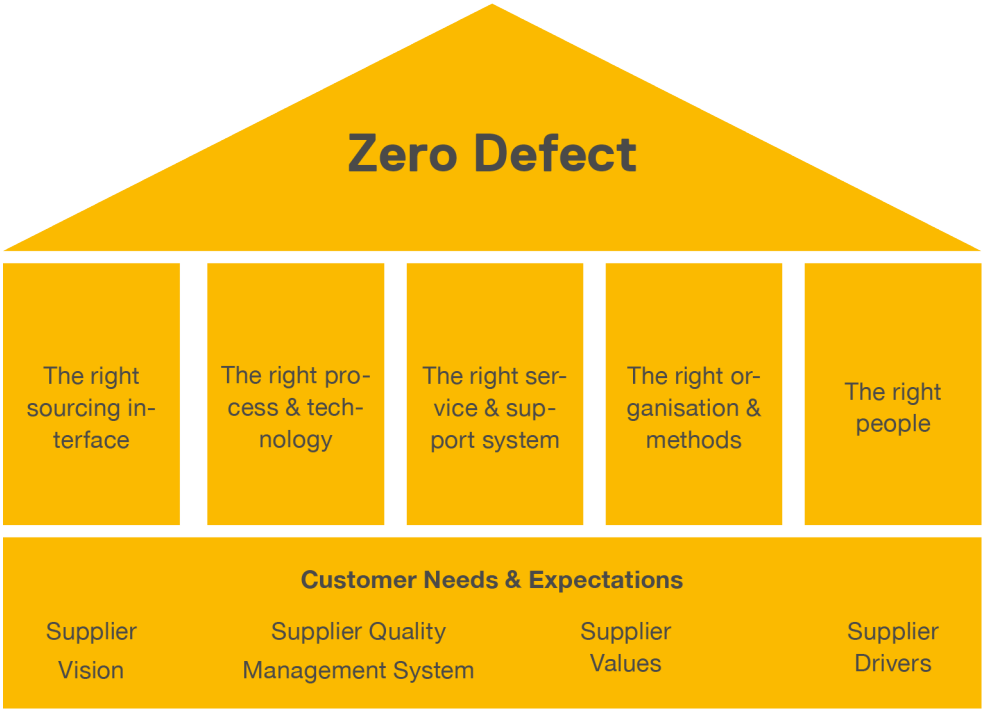
The five pillars of Zero Defect

As we have already discussed, to achieve and maintain ZD in manufacturing, there are five requirements that must be fulfilled:

- the right sourcing interfaces
- the right process and technology
- the right service and support systems
- the right organisation and methods
- the right people



The requirement to achieve ZD enforces each pillar to contribute to fully support the house, resulting in ZD if all is well. If any of the pillars is weak, then the ability to carry the massive weight that is ZD will be compromised. It is therefore critically important that all pillars remain strong and all contribute to carrying their share of the responsibility that ensures a stable ZD environment.

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The right sourcing interfaces

You must ensure that you demonstrate a total commitment to quality and an ability to deliver constant world class performance.

You shall sign and commit to the Ewellix Qs (Quality Standard for suppliers) and operate according to the conditions laid down by this requirement.

You must also ensure that you support Ewellix's business need. This need includes on time deliveries and defect free products.

Quality Assurance and Process Engineering are responsible for evaluating whether a supplier needs to be followed using the APQP+ for suppliers' process.

Agreements on drawings and specifications

Ewellix Quality Assurance and Product Engineering shall provide complete and valid technical documentation (such as drawings, DFMEA, application envelope and data, and any applicable visual standards). Purchasing shall submit these to the suppliers and Quality Assurance has the responsibility to verify that the suppliers formally agree with them. Quality Assurance shall manage supplier comments or deviation requests.

In addition to the above, Quality Assurance shall also review the extent of specifications (over or under specification) planned for each critical component of supply. There may be a request to modify the specifications depending upon the capability of the suppliers' processes and the requirements of the product within the application. If a change request is needed then this shall be formally documented in the relevant ECM (Engineering Change Management) system. Identification of critical or significant parameters Throughout the complete documentation chain, Product Engineering shall take responsibility for identifying critical, significant and high impact characteristics. Quality Assurance shall verify with suppliers and their sub-suppliers that their specific quality planning activities (FMEA, control plan, and PPAP) take these characteristics into account. The documentation chain discussed includes

Design FMEA, Process FMEA, control plan, work instructions, Ewellix customer specific requirements, Ewellix requirements, etc.

Capability

Ewellix has the responsibility to monitor the capability of certain key parameters. These parameters are typically (but not restricted to) those identified as critical, significant or high impact characteristics. If the required Cpk (as per QT 1) cannot be met, then it is the responsibility of Supplier to establish adequate control methods and verify that they are effective.

Product approval

The PPAP process is required for all purchased components and is under the responsibility of the supplier technical assistant. In the event that this role is not available, then the responsibility reverts back to Quality Assurance. Verification activities and any appropriate corrective actions shall be completed before the start of series production.

Quality Assurance shall define the PPAP requirements as per the relevant international standards. Quality Assurance provides PPAP approval and formal records of such shall be kept locally. As required, the PPAP process and any necessary documentation shall be recorded in the appropriate Ewellix database.

The results of supplier PPAPs have to be used to evaluate the level of incoming inspection required. The supplier PPAP must be verified at Ewellix, prior to the approval being granted.

Definition of supplier process routes

Process routes for raw materials and forged rings are to be approved and documented by Supplier and sent to

Ewellix for approval.

Ewellix shall refer to the approved route in purchasing orders raised for prototypes, PPAP and serial production components.

Suppliers shall be informed of the approved process routes with clear instructions for change control.

Handling of complaints

Supplier complaint handling shall be performed in line with the supplier NCC procedures. This includes verification of Corrective action report Why analysis and reporting and effective implementation of such. The NCC database is used to issue, track and close official supplier complaints. Any repetitive complaints need special attention using the escalation approach as described in the procedure. Quality Assurance shall ensure that appropriate follow-up activities are employed.

Supplier performance follow-up

Supplier performance shall be regularly reviewed, ac-cording to the Purchasing Qc procedure. This includes communicating to suppliers their level of performance and requiring improvement actions when performance is considered unsatisfactory. This shall be followed- up to ensure that information is used for improvement activities with the objective of development towards ZD.

Approval of manufacturing tools

Formal approval by Quality Assurance on the availability of tools at the suppliers is required prior to series production. This shall include a review of perishable tools and targeted tool wear. Formal records shall be kept.

Any suppliers used for the procurement of critical tooling that influences the final Ewellix product, shall be carefully evaluated and formally approved. A tooling quality planning process shall be in place and all critical tooling shall be subjected to an approval process at Ewellix prior to use in series production. Tooling modifications must be carried out systematically and necessary disciplines should be defined by the factory's Quality Assurance.

Purchase orders and quality agreements

Purchasing shall only send series production orders to approved suppliers for the approved process route and for officially approved products. This applies also for the quality agreements with exception for the sample orders, prototypes and PPAP.

Quality Assurance will verify and report any deviations to Supplier Excellence for their correction.

Purchasing shall place orders with reference to valid technical documentation.

When applicable, this will include the identification of Ewellix approved raw material source(s).

Supplier ZD plan

The plan is required from suppliers that have been subjected to a ZD audit with corrective action requirements. The ZD audit can be conducted by a certified auditor either from Supplier Excellence, Quality Assurance, or by an Ewellix certified inspector at the supplier.

Quality Assurance verifies that the corrective actions have been implemented to an adequate standard. The ZD plan, ZD audit, and corrective actions shall be documented.

ZD audit

A ZD audit is deemed necessary for any of the following situations:

- For new suppliers that are involved in homologation.
- For existing suppliers that are involved in PPAP for an unapproved process routing.
- For suppliers that are selected through a risk analysis which has been managed by factory Purchasing using the supplier monitoring system.
- For suppliers with a first time NCC (1st NCC in 12 month period).

Supplier monitoring

The factory Purchasing shall evaluate all active major suppliers (global and local major) for their factory, on a minimum frequency of twice a year. This evaluation shall then serve as the source of recommendation for deployment of ZD audits at higher risk suppliers.

Supplier PPAP process and ongoing quality

Supplier processes shall be periodically audited in cooperation with Purchasing. An emphasis shall be placed on effective implementation of the agreed process flow and control plan, and on the extent to which mistake proofing, preventive maintenance, tooling quality, sub-supplier quality process validation and problem solving processes are used and validated. Some of these items would have been included in the PPAP submissions to Ewellix and form an integral part of the Ewellix specific requirements. Any deviations should result in immediate corrective actions and result in potential consequences against the supplier, such as new business hold conditions being applied.

The right process and technology

The main objective of the right process and technology is to understand how these factors interact and affect processes and how you can manage these processes to make them behave in the way you want them to. Ewellix's aim is to achieve Zero Defect. The key factors involved are:

- Operational personnel within the processes
- Material and information used as process inputs
- Machines, equipment, and tooling used for the execution, measurement, control, and monitoring of the pro-cess.
- Methods for setting the approval criteria, documents used during processing, and the general work environment

Green flow coverage

Green Flow Coverage (GFC) requires that transportation systems be covered (protected) to avoid the reinsertion and possible mixing of product, following an inspection operation. It could also be described that the intent of "green flow" is to avoid mixing products of known quality (good parts) with products of unknown quality (potentially bad parts).

The biggest single reason for defects being passed to our customers is the mixing of good parts with bad after the inspection devices have approved the product. To prevent this from occurring, the GFC concept shall be implemented.

A detailed mapping shall be created for each manufacturing channel which details the checking apparatus and the status of the GFC for the device. Where the GFC concept is lacking, there shall be a plan with a clearly defined timing to bring the local area into line with the GFC concept.

GFC shall not only be limited to inspection devices. Any location in the manufacturing channel where there exists a risk of parts being mishandled should employ the GFC concept.

Typical characteristics of GFC include the covering of chutes and flexlink with a simple plastic roof to make it impossible to re-inject or remove any parts or create a situation enabling the mixing of parts. Some example

photographs of the GFC concept being applied are shown here below.

The ‘green flow’ shown here literally shows the green plastic being used to prevent rings being removed from the flexlink. This also prevents rings of unknown quality being inserted. This example shows the flexlink upon exit from an inspection device.

Here we see an example of a controlled insertion point on the flexlink. This door is used to collect master samples after a calibration routine has been performed, but in a controlled manner. This makes the operator think twice about the task he/she is about to perform.

Scrap without compromise

Scrap Without Compromise (SWC) assures that defective parts are correctly removed from the channel, thus avoiding the mixing of good and bad quality parts. SWC forces the scrapping of rejected parts, usually with controls that require the scrap box to be locked and very clearly identified.

The focus shall be on improving measurement and inspection devices in terms of both reliability and capability.

Machine reliability

Machines and processes need to be reliable. The higher the level of reliability, the less chance there is of making outliers. Outliers are parts which lay outside the tolerance of the common distribution of parts made during normal operating conditions. Outlier parts are often manufactured when resetting activities occur or when consumable tooling is changed on a machine, such as turning tips, grinding wheels, etc. Poka yoke devices should be used to prevent any outliers being delivered to the customer.

Process capability

Statistical performance of the key operations within the manufacturing channel must be measured and where necessary, improved upon. All Cpk and Ppk values need to be in line with or better than the requirements and/or any specific customer requirements that are in place. Capability studies shall be performed as needed to assess this information on a regular basis, and this data shall be used to support continuous improvement.

Measurement equipment reliability

It is of paramount importance that you are able to trust that your inspection devices are able to sort good quality parts from bad quality parts. To enable this to happen you must strive to ensure that inspection devices are maintained and cared for in the appropriate manner.

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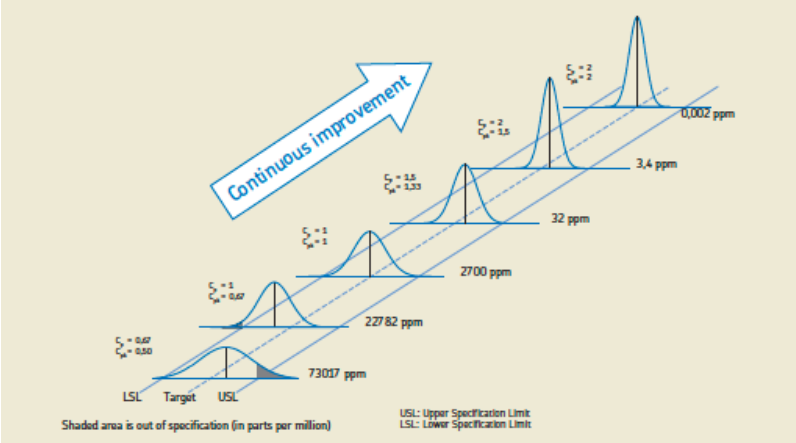

Chart from the Ewellix booklet showing how ppm defect levels reduce with the corresponding increases in process capability.

Scrap box which is painted red to clearly identify the bad quality condition of parts inside. Notice that the box is locked to avoid scrap parts being recycled into the production process.

Very clear signage to signify ‘scrap without compromise’.

Measurement systems analysis

Measurements Systems Analysis (MSA) is to be statistically assessed and measured in terms of r&R (repeatability and Reproducibility). Results need to be in line with or better than the specified requirements. This ensures appropriate machine judgment and avoids ‘false rejects’ being created. In cases where many ‘false rejects’ are created, the inspection cost ends up increasing significantly as further inspection operations are usually required to ascertain the levels of and sort out the ‘false rejects’. MSA studies need to be repeated regularly to detect deterioration over time. The minimum requirement shall be annually, but it is suggested that key inspection devices are covered more frequently.

Measurement is knowledge and what cannot be measured, cannot be controlled either. When building ZD practices into a channel the roles and responsibilities for measuring equipment, taking measurements, and using the results for analysis are of extreme importance. Selecting, planning, setting, calibrating, repairing and servicing activities fulfil a basic need for measurement in the manufacturing environment, but to do so reliability and consistency are essential if we are to achieve ZD.

All critical measuring equipment should be under a suit-able preventive maintenance programme to check for consistency of operation.

100% inspection / poka yoke devices for outliers

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100% Inspection activities are to be employed when ma-chine capability levels do not meet the necessary requirements as demanded by Ewellix. This is to ensure you deliver parts of the correct quality, but also to investigate the level of defective parts produced. 100% Inspection is expensive and if performed by humans only 60-70% effective so there should not be an over-reliance placed upon 100% manual inspection in the long term.

Poka yoke devices shall be deployed as appropriate in the manufacturing channel to avoid any outliers escaping.

Ergonomic workplace

There are many ingredients that need to be present to achieve a totally ergonomic workplace, but it is essential that there is:

- adequate lighting,
- correct and relevant information displayed,
- orderliness and cleanliness.

An integral part of achieving ZD is the management of the workplace. The process layout, adopted ergonomics, placement of controls, procedures used, and disciplines practiced should be thoroughly evaluated.

The resulting output and any identified non-conformities should be assessed against the desired objective of the entire workplace. A concept such as ‘a place for every-thing and everything in its place’ should be used and the workplace should be frequently audited to ensure that it is both orderly and appropriately clean.

Mistake proofing methodology should be employed to prevent mistakes being made with work-in-process

(which is known as WIP). These are products in various stages of manufacture and tend to be offloaded at key operations in the channel to ensure for bottleneck throughput efficiency. It is critical that we ensure that any suspect, non-conforming, or scrap material is immediately removed from the production flow.

Employing kanban, 5S and low inventory principles will also improve the effectiveness of the workplace.

Example of an orderly tool chart where it is clearly defined which tools go where and the correct levels of protective equipment that needs to be worn.

Cleanliness

Cleanliness of the workplace and specifically its ma-chines is the responsibility of all personnel in operations. A clean workplace provides evidence of a professional manufacturing environment and demonstrates the dedication and commitment of the people employed there.

Tool management

Tooling shall be managed according to specifications and if effective, will form the base of a ZD manufacturing process. Deviations should be handled in a controlled way. Tools should be made available when needed and

properly stored when not. Damaged tools need to be re-placed or repaired immediately, and special tools need to adhere to any calibration requirements placed upon them.

Tool design and approval should use a concept very similar to the APQP+ process (Advanced Product Quality Planning) to minimise any errors during and prior to series production. The approval of production parts from new tooling shall be closely monitored.

All tooling used for critical operations should be verified periodically for conformance to quality. Suitable tooling management audits should be considered to verify the condition of critical tooling and systems employed in testing the tooling. A system should be established to re-place any worn-out or faulty tooling. Tooling availability should be restricted and monitored and should be stored outside the manufacturing channel.

Modifications and changes to tooling of one product type should also be extended to the other product types, as required (using the 'look across' approach). Obsolete tooling shall be disposed of in a timely manner.

Suppliers used for tool manufacturing or procurement shall have adequate supplier quality standards governing the materials used and the way they are processed. Unauthorised and unapproved tooling may not be used for series production.

Typical example of a clean, well laid out work environment. There is a central gangway that is free of obstruction and no evidence of spillages of major coolant leaks. The area is well lit from central overhead lighting and the floor is marked for appropriate boxes of components (WIP).

The right service and support systems

Machine operators need centralised support from maintenance, process engineering, quality, and production management. If all personnel and processes follow the same ZD principles, then the chances of success in achieving our ZD ambitions will be maximised.

Handling of scrap

The handling of scrap shall be described (preferably with visual aids) in all locations and made extremely clear in all procedures.

All non-conforming materials shall be secured in suitable scrap containers and locked to ensure they cannot be easily retrieved and mixed. The reject box (preferably in red) should be clearly labelled to show what is contained inside (e.g. bore grinding scrap – rings oversized).

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Handling of rework

Reworking of parts is not encouraged as it often leads to mistakes which result in bad quality parts being mixed with good quality parts which in turn results in customer complaints. Any rework operations that are approved by local management shall be described with clear work instructions (including pictures where relevant) and displayed in all relevant locations. Simple operator training classes should be given to make them aware of the rework being undertaken and why it is necessary. To avoid mixing of parts, rework shall be performed in locations well removed from the associated operation.

There are 2 levels of SWC that can be employed. These are:

- • 'Y' condition = SWC
- • 'X' condition ≠ SWC

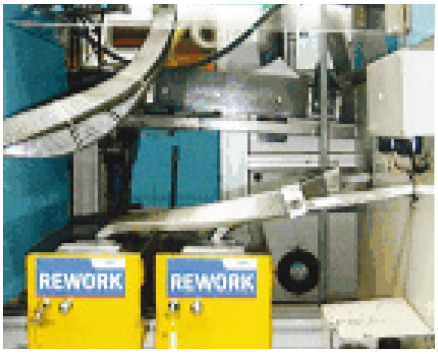
For the 'Y' condition, parts are automatically scrapped if rejected from an inspection device. The scrap chute

(when in measuring mode) shall be set to automatically reject. Upon receiving a signal that the measured part is 'good', the scrap chute should open to allow the part to pass. This concept ensures that in the event of the scrap chute malfunctioning, it will fail in a safe manner protecting both you and Ewellix.

There will be some situations where the cost of certain components makes it not cost effective to throw away the complete assembly. In these cases it is permissible to break down the assembly and scrap the relevant parts while salvaging the "innocent parts". Typically this would mean scrapping the rolling elements and any cages and recycling the rings. For the "X" condition, some reworking of parts is allowed. Reworking or more commonly

re-checking can be authorised, but this should be per-formed outside the channel and under controlled conditions. As already discussed, reworking is not an encouraged process as it often leads to mixing of parts, and customer complaints. Reworking should only be considered when measuring equipment is found to be not capable, or the cost of scrapping all components is prohibitive. These should be time limited options and removed when the process is repaired. The optimum condition for SWC is the "Y" condition, and any processes initially regarded as "X" should have a demonstrable plan to achieve the "Y" condition.

Example of scrap boxes in the manufacturing operation. They are both labelled and locked and in bright red colour. These scrap boxes are for rejects from manual inspection operations.



The 2 rework collection boxes can be seen here clearly identified, for collecting parts for rework using a local formal procedure.

Transport systems

Transport of parts within the channel must be designed to minimise handling damage and possible dirt contamination. Any working-process "buffer" requires the presence of detailed work instructions to clearly detail how many parts there can be allowed, where they are to be placed and what inspection is necessary before reinserting these parts back into the channel. It should be extremely clear both where these pieces were removed from, and also where they should be reinserted to. Any buffer stocks should be kept to an absolute minimum and

any cases where the buffer capacity has been exceeded (from those stipulated) requires approval from the local production and quality management.

Identification of material

All components that have been offloaded away from the normal flow of parts within the manufacturing channel need to be identified to signify their current status of machining/processing.

There is some key information that needs to be shown which includes:

- part designation or reference
- current stage of machining (could be last process or next process required)
- date the parts were removed from the channel
- quality of part contained
- status of parts (good/suspect/scrap/etc.)
- any other special instructions.

It is helpful if identification of the parts is made using co-loured identification cards to make it clear what the intended destination of the parts is.

Typically, green is used to signify ‘good parts’ with known product quality which are destined to be reinserted back into the channel. This would typically include buffer stock. Yellow is used to represent parts that require further inspection, i.e. the product quality is either unknown or suspect. Red is used to indicate that the parts are scrap or to be disposed of.

When offloaded parts (or buffers) are reinserted back into the normal flow, they shall follow strict first-in-first-out

(FIFO) principles and take into account the status of the parts.

Specific requirements

Any specific requirements need to be made available in the operation and included on all drawings, the Process FMEA, any necessary work-instructions, etc. Typically if these requirements are not made extremely visible then they will not be respected and not followed.

Calibration systems

Calibration of all measuring equipment needs to be in place and records need to be kept which include where the piece of equipment is being used, and when it is due for its next calibration. These records must be traceable. All measuring equipment need to be well maintained, and the channel operators need to clearly understand how to use it in order to avoid making product deviations by error.

Resetting

When resetting a production channel to produce a different bearing reference, this requires a system to prevent the release of ‘set-up parts’ back into the channel. Typically these parts would show up as outliers and could be massively outside the required production tolerances. First-off inspection needs to be performed and documented. For ZD production processes, it is mandatory that product parameters that do not undergo further changes (e.g. are not machined) or modifications in the subsequent processes, undergo a satisfactory ‘first-off approval’ before they are released for series production. These processes should be reset and/or fine tuned prior to release for series production. Processes that have repeated failures in meeting the ‘first-off approval criteria’ should be submitted for capability improvement or pro-cess re-design (longer term action). Key events requiring set-up approval and sign-off are:

- channel changeover,

- process change,
- material change,
- rectification/refurbishing of a machine, from a serious breakdown.

Breakdowns

When major breakdowns of production machinery occur, this requires secured procedures to ensure that defective parts are not manufactured or introduced into the channel. When restarting the channel after an unplanned stoppage such as this, additional checks are needed to verify that parts are in conformance with the requirements. On a lesser scale but equally important, tool change intervals need to be defined and monitored to avoid tool breakages that could cause defective parts to be produced.

Hidden factor analysis

The Hidden Factor Analysis (HFA) aims to document events and activities that happen with irregular time intervals. These events are typically linked to:

- products audits
- reworking
- scrap
- changeovers

During the above mentioned activities, there are process routes and paths that do not normally happen to components.

For example, if you consider product audits. An inspector would arrive at the machine, remove a part after it has been processed, and take it to either a measuring station or an alternative place (such as a laboratory) where measurements will be taken to assess the conformance of the part against the requirements.

Following this inspection, the part can either be returned to the channel and placed back on the flexlink from the point at which it was taken, or scrapped into an alternative location (it could also be placed in the incorrect location).

The analysis from the HFA should be fed directly into the Process FMEAs and this in turn should expand the Process FMEA sufficiently so as to assess further risks and opportunities for improvement. Enhancing your defect prevention abilities begins with understanding the hidden factors in your environment and then applying effective measures to deal with those factors.

As already discussed, there are several activities that happen in the channel which are considered to deviate from the standard. By far the biggest risk occurs when parts are removed from the flexlink and then later re-turned. This could be for a number of reasons but the most common would probably be for the operator to per-form a manual inspection on a piece of gauging equipment. Once removed from the channel and measured, the operator then makes a decision whether the part is good or bad.

A good part should be placed back in the channel from the point it was taken. A bad part should be immediately scrapped to avoid it being mixed with good parts and then being reinserted into the channel by mistake.

If you consider that more than 75% of all customer com-plaints are caused by people mishandling parts, then it seems appropriate that you need to be extra sensitive to all possible causes and opportunities where mishandling could take place. Typical opportunities for mishandling to arise include:

- Parts that are mixed during changeovers in the channel.
- Scrap parts that are not handled according to an established SWC instruction (defective parts not placed in the defined
- scrap container).

- Rejected or ‘on-hold’ parts that find their way back into the process because there are ‘too many’ to scrap.
- Products involved in an invalid or unapproved alternate operation that bypass a process sequence (the opera-tor put the part back on the channel in the wrong place).

HFA is to be applied as a technique of evaluation and analysis by expanding the basic flow diagram to show every possible flow within a channel that a component or a production part could make during processing.

The analysis begins with a regular process flow diagram that is expanded to incorporate all possible part activities, including:

- Manufacturing – forms the more basic part of a process flow diagram to show the natural sequence of machining operations.
- Moving/transportation – identifies what is physically happening to the parts. E.g. are they loaded or un-loaded from a machine? Is there some type of manual handling operation in place?
- Storage/retrieval – typically shows where reinsertion points should be into the channel and where WIP should be stored.
- Inspection – any time the condition of the part is verified, and can include both manual and automatic inspections. Master samples and calibration master should show up here as well, if used.
- Reworking – any reworking activities that are under-taken whether they be in or out of channel. Additionally, inspection activities that take place during reworking should be shown and the actual point where a re-worked part is re-entered into the channel.
- Scrap/containment – once the decision has been made that the part is scrap, then how is it contained and finally disposed of? Is there an element of control in this?
- Changeovers – during resetting operations there are many parts in the channel and quite often these parts are different references which can be similar. Control needs to be in place to identify the last in and first out part of the next reference after resetting. The machines need to be emptied of all components, including any which have fallen inside the machines.

Once the hidden factor analysis has been fully completed for a channel, then all possible paths that a part can take during its manufacturing journey should have been identified. This information then feeds the Process FMEA which in turn feeds the control plan. The intended aim of the HFA is to facilitate the creation of an extremely robust control plan which focuses attention on as many risks as is possible, to minimise the chances of delivering bad parts which ultimately cause complaints.

First-in-first-out

First-in-first-out (FIFO) shall be applied to all products, components, and materials that are used within the manufacturing operation. An efficient FIFO system helps to keep the products/components flowing through the factory in the order they were produced, which also means that if any problems are discovered, then it will be easier to maintain control over what was made when and more clearly establish clean points based on production dates.

Another important reason to employ an efficient FIFO system is to reduce the risk of rust on components. This condition becomes more apparent in areas of increased heat and humidity.

Process failure mode and effects analysis

Process FMEA need to be readily available, reviewed and updated on a regular basis by the core document owner. Multifunctional teams shall be used to create and review PFMEAs and they should cover the entire process from receiving through to warehouse delivery.

Continuous improvement programmes

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Process improvements are initiated by measuring how effectively the manufacturing processes are matched with the product requirements and both the customer needs and expectations. It is extremely important that employees understand how their actions affect the customers' perception of quality and performance. Process improvements should lead to reduced costs, improved quality, or better service to customers.

When desired levels of efficiency or quality output are not achieved on a consistent basis, then process improvement is required. Process improvement is essential when targets are not met for:

- failure costs such as scrap, loss and rework (SLR),
- customer returns and warranty,
- chronic and repetitive non-conformances,
- machine downtime and inefficiency

Process capability needs to be assessed to identify pro-cess variables causing undesirable or excessive variation and corrections and improvements need to be planned for and actioned as appropriate.

Six Sigma projects can be used to make improvements in some more complex situations. All personnel involved and/or supporting manufacturing, engineering, and quality control activities shall be adequately trained in 'problem solving' methods and the various tools which sup-port them (e.g. Six Sigma, 8d problem solving, 5 Why, Cause and Effect diagram, Five4U, etc.).

Event logbook

An event logbook is used to record the major activities and details that occur within the hours of a manufacturing shift. The key items should aim to give a brief history of what actually happened during the shift, so that this can possibly be reviewed at a later date to give credence to what went on and why. The kind of items that need to be documented should include:

- Were there any key breakdowns to machinery?
- Which operators were present on that shift and where they worked?
- How many pieces were made?
- What were the scrap levels?
- Was there any resetting performed?
- Summary results of any process/product audits.
- Brief details of any meetings and/or training.

The event logbook is typically a one page document that is completed during the shift as events occur. It could be that all shifts from a certain day are on the same document. The details could help identify why the output is reduced (machinery is broken down, reduced number of operators through sickness, 2 hour meeting, channel re-setting to another reference, etc.), or why the scrap levels were increased (bad quality of incoming components, bore grinder malfunction and produced many oversized parts, tooling worn and new item not available for another 2 days, etc.). The level of detail needs to be clear but not too deep. If nothing much of interest happened during the shift and production output was as expected, then the event logbook should clearly state this.

Specialised audits

All critical and special processes in manufacturing should be subjected to specialised process audits to identify technological and process deficiencies that could cause non conformances. Specialised process audits could cover the grinding process, heat treatment, orderliness & cleanliness, tooling management or TPM.

The factory quality manager should coordinate these audits with the concerned process specialists and improvement activities should be followed-up properly. Layered Process Audits (LPA) should be included in this scope and be performed by the management team of the local unit. The intent of LPA is to perform many small audits (less than 1 hour duration) and to focus on specific areas of manufacturing. The focus highlights areas that

are either not being maintained at the required level of performance, or areas that require immediate corrective action. Either way the output should be small improvement plans and projects that contribute to the continuous improvement process in a very live way.

These pallets are stored in a recognised buffer area inside a production channel. The stock to use first is at the front, and each conveyor is loaded from the back.

When each conveyor starts to get low on parts the floor colours become visible showing yellow for low on stock and red for almost empty.

The right organisation and methods

The objective of the right organisation and methods is to provide those tools that support the delivery of ZD to customers.

Transportation is key to this as it protects the customer requirements, and often is the first thing the customer will see when the products arrive at the customer location.

The way in which you deal with any customer complaints will also count towards the reputation. Complaints should be dealt with in a professional logical and methodical way, without taking too much time so as to appear you are not considering the complaint important. Complaints of a reoccurring nature are extremely displeasing and you should strive to ensure that you identify and remove the causes of complaints following the problem solving process discussed shortly. Any actions identified shall then be replicated across all other relevant processes to remove the risk of a repeat incident.

The Non Quality Cost (NQC) is directly linked to the ZD approach in that the lower the NQC the bigger chance we have of achieving ZD. NQC is reduced by ensuring SLR at extremely low levels and focus on delivering parts that meet customers' requirements.

Operator Driven Reliability (ODR) and Total Preventive Maintenance (TPM) are tools that can be used to drive the manufacturing channels and give a very clear direction and responsibility in ensuring the people are in the right frame of mind to keep doing the 'right things right'.

External transport

While products are being shipped to the customer location, the transport method needs to ensure that the integrity of those products is not compromised in any way.

Packaging also affects the quality image of the product, and the customers' perception of quality will be influenced by how the packaging looks and how presentable the product identification marking is. The need for ZD packaging & identification is as important as any other aspect discussed previously.

Experience has shown that improper or inadequate packing is a root cause of many defects and complaints.

Each packaging facility or channel should be equipped with adequate specifications, equipment, hardware, and

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methods to control and monitor the packaging process.

Packaging and identification shall be considered a part of the normal manufacturing flow, and relevant controls and monitoring activities shall be included in the quality control plan to ensure that a ZD approach is maintained.

Product and process specifications

All relevant specifications need to be available at the workplace. Operators need to understand and have easy access to them. Graphical displays of the specifications are preferred using pictures where appropriate. Regular training and updates are needed to ensure the under-standing is up-to-date and the approach never compromised. Any work instructions should be short and concise and any changes should result in operator training to check and verify the understanding.

Non-conformance complaints

The Ewellix recognised way of handling NCC from customer is through the TER (Technical Error Report) data-base.

To identify the root cause(s) and establish sustainable corrective actions for the avoidance of any reoccurrence, the 8d process shall be applied. The 8d process defines a corrective action methodology and emphasises team synergy because the team as a whole should be better and smarter than the individual. The 8d process is a problem solving methodology for product and process improvement, and is complementary to the Ewellix Six Sigma programme. The nature and complexity of some NCCs may even require a Six Sigma project to bring about the necessary improvement.

The following are the eight defined steps of the 8d process:

- **d1** – Use of a team approach/people with the necessary process & product knowledge, allocation of time, ensure that responsibility & authority and skill in the required technical disciplines to solve the problem and implement corrective actions is available.
- **d2** – Description of the problem/use of photos of what are ‘good’ and ‘bad’ parts, full details about the failure.
- **d3** – Implementation and verification of interim containment action(s)/what is being done to protect the customer from the defect until permanent corrective actions are implemented.
- **d4** – Definition and verification of the root cause/brain-storming and 5 Why analysis to show what went wrong.
- **d5** – Verification of the corrective actions/ confirmation that the corrective actions will resolve the problem for the customer and will not cause any undesirable side effects. Shall be shown to be the best of all the alternatives.
- **d6** – Implementation of permanent corrective actions/choice of on-going controls to ensure the elimination of the root cause(s). Detection of any undesirable side effects and validation of the same.
- **d7** – Prevention of the problem reoccurring (action ex-tension to similar processes using look across method-ology)/modification of any specifications, update of training, review of the workflow and improvement of work practices & procedures to prevent recurrence of this and all similar problems.
- **d8** – Recognise the team achievement/ celebrate the successful conclusion of the problem solving effort (internal communication and sharing of knowledge & learning). Each of the eight disciplines is continually re-visiting the questions considering what, why, where, who, when, how much, how many and how often.

Preventing reoccurrence of defects

Prevention activities can be realised and greatly improved by the use of poka yoke devices and a formally documented lessons learned approach. The risk of defect reoccurrences must be reduced and eliminated.

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Carry-over of improvements (look across approach)

When a corrective action process is nearing completion it is imperative that you consider if there are any similar in-stances in your facility where you could have the same problem. This check should be documented to ensure you have looked across all areas considered to be a further risk. Ultimately this information should be shared around factories making similar products, with similar processes to make the look across approach complete. Effective root cause analysis is a prerequisite to avoid the reoccurrence of defects.

The systematic communication of goals and results

The goals and results of the manufacturing channel need to clearly communicated from the management to the employees. These need to be clearly understood by the employees to ensure the appropriate commitment as to how their actions can impact the success of the unit in terms of finance and ZD. Channel performance matrices need to be available locally.

Generally, as we move through the product development cycle, the costs associated with correcting problems escalate on a 10:1 ratio for each phase. It is therefore advantageous to spend as much as possible in design as it will prevent spending considerably more in-service.

Cost of non quality

The cost of non quality concept needs to be made avail-able and understood by all employees. Trends over the past months/years need to reflect any forthcoming improvement plans.

The term ‘cost of non quality’ refers to the costs associated with providing inferior products or services and then having to possibly correct them.

Similar terminology within industry includes Philip Crosby’s ‘price of non-conformance’ and Joseph Juran’s ‘cost of poor quality’.

Research shows that the costs of non quality (e.g. re-work, returns or complaints, reduced service levels, and lost revenue) can range from 15%-40% of business costs, and Return On Quality (ROQ) has dramatic impacts as companies mature. Most businesses do not know what their quality costs are because they do not keep reliable statistics on them. Finding, correcting and reducing these costs can require a great outlay of re-sources.

Typically, the cost to eliminate a failure in the in-service phase is 100 to 1000 times greater than it is at the development or design phase. Effective quality management decreases production costs because the sooner an error is found and corrected the less costly it will be.

There are several items to be considered when aiming to establish the cost of non quality. These are:

- **Material losses** – the cost of losses in material at its standard cost value, including the scrapped material without value added. This applies to components and materials in manufacturing stock, all WIP and finished stocks. It does not include pre-defined process losses which are generated due to the

process type, such as steel bar ends and billets from a bore conforming operation, rubber losses from moulding operation, etc.

- **Added value** – the cost of added value in scrapped materials. This includes scrapped material which has passed the first operation when value is added to the component standard cost, and the cost of further machining operations on scrapped parts. The later in the process the scrap occurs – the greater the added value shall be.
- **Internal sorting** – the cost of extra inspections that are not normally considered standard within the production process, and are typically made outside the channel. This applies to all sorting activities inside the factory and/or the warehouse. It does not include sorting activities from customer complaints, recalls or field returns.
- **Premium freights** – the cost of extra shipments to the customer, that are outside the normal delivery process, e.g. air shipments. This includes all shipments outside the normal delivery process. It does not include extra shipments due to customer complaints, recalls or field returns.
- **Customer complaints** – the cost associated with a defective part at the customer, e.g. containment, sorting, replacement of products, charge backs from the customer, internal NCC handling and investigation costs. This applies to all justified and non justified zero hour complaints (where zero hour represent a product not having been used in the application). Recall – the cost associated with a recall campaign, e.g. containment, sorting, replacement of products, charge backs from the customer and any investigation costs.
- **Field returns** – the cost associated with parts returned from the field that are considered to be in warranty, e.g. justified bearings, technical factor agreements and investigation costs. This applies to all justified and non-justified field return failures.
- **Deliveries** – deliveries of the unit in PS cost from production and services including sub-contractors.

To reduce the costs of non quality within a factory there must be a planned programme of improvement that reflects gathering information on the above mentioned topic areas.

This needs to be followed-up on regular intervals to ensure that the chosen actions for improvement are having the desired end effects.

Channel leadership and clear responsibilities

It is important for the channel and its management to know who the correct people to turn to are, when needs arise. There should be a visual reference of which employees are qualified to operate which processes. There are many ways to demonstrate this, but something similar to what is shown below is a good start. Organisational diagrams and defined responsibilities need to be reflected in work instructions and skill matrices need to be made available and be clear in the information they are presenting.

TPM and ODR

All machines and equipment shall be placed under a Total Preventive Maintenance (TPM) programme. The TPM will include periodic checking of the machines and equipment for damage, deterioration, effectiveness of daily maintenance, missing accessories, supporting tooling and that any safety controls are functioning correctly.

The effectiveness of any maintenance repairs shall also be suitably measured to ensure that the maintenance function is performing its required role. Effective cooperation and the free flow of information between operators, maintenance and management is essential in bringing the process back to a stable level following a breakdown or situation where a repair has become necessary.

Effective maintenance leads to the improved reliability of production machinery and also reduces the ability of the process to produce defects through reduced interruptions in manufacturing. This is the reason that maintenance should be carried out in a planned and organised manner, rather than carried out on an ad hoc basis. Maintenance activities should be periodically audited. Operators should be considered a part of effective maintenance in the application of the Operator Driven Reliability (ODR) concept.

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A core element of the ODR concept is the 5S methodology to implement workplace organisation and standardisation. The goal of 5S implementation is to reduce inventory, increase efficiency in the workplace, reduce time searching for parts or tools and reduce the spillage of oil, water, and loss of compressed air. It furthermore has a vital influence on the reduction of accidents and defects in the channel and focuses the channel on meeting ZD targets. The individual components of the 5S methodology are:

- Sort – remove what is not needed and keep what is needed.
- Set in order – place things in such a way that they can be easily reached whenever they are needed.
- Shine – keep things clean and polished and do not al-low or accept trash or dirt in the workplace.
- Standardise – perpetual cleaning by maintaining a clean work environment.
- Sustain – teach the attitude of commitment towards all undertakings to inspire pride and adherence to standards established for the other four components.

Model control plans

Control plans for all processes shall be available and followed. All information contained within the control plan is part of the PPAP package and is thus part of a contract. Deviations from control plans are allowed only on a temporary basis and deviations need approval from the local quality organisation. Prolonged deviations should be considered as engineering changes and fully documented in a formal way. Risks should be fully analysed and customer approval may be required.

The right people

The human factor is one of the most important and fundamental requirements in building and achieving Zero Defect. It is a well known fact that human errors are the largest contributor to the total number of defects produced, so it is critically important to have the right people and ensure these people have the right competences to be able to do their jobs both efficiently and effectively.

Competence

Competence on-the-job requires that today our work-force takes a more multi-skilled approach, and training plans and their follow up need to reflect this.

This demands an environment where delegation and empowerment become the norm in establishing and stabilising excellence in work teams. License to drive operative tasks need to be formally established (especially for new channels or new employees) to ensure that basic competence levels are gained before ‘letting them loose’ in an environment where the lack of experience could result in a behaviour not in line with maintaining ZD.

Once new operations are started (or in the case of new employees entering existing manufacturing or support operations, e.g. metrology laboratory), it is essential that a formal process be put in place to verify that their competences and skills are oriented towards a ZD approach.

In a similar way to driving licenses for cars in the real world, this methodology should help to safeguard ZD pro-cesses by providing training and skill development in those areas considered to be necessary. The result of this should be that the new employees gain knowledge and experiences that will help influence their behaviours when they are working in the production channel.

A list of operations and the skills required to perform them properly should be posted within the channel and all operators working there should have a formal assessment of which skills they currently have and which further skills they require.

Experienced operators or support personnel can help their colleagues in attaining the new skills and knowledge, and thereby act as trainers and mentors in the gaining and development of competence. All training shall be documented and concluded with a formal assessment to establish that the skills and knowledge has been retained and that the competence has therefore increased. Only after a successful assessment can an employee

begin working with the newly gained competence areas by themselves.

The human factor is one of the most vital elements in building an environment for ZD and should include both employees and management. The four main factors that collectively influence and directly affect the ZD performance are:

- Leadership – ZD requires that the customer be given top priority in the channel and leaders need to lead their teams and inspire them to achieve the target laid down.
- Operational discipline – to achieve a constant level of ZD you need to have operation standards that you consistently meet. These include procedures, work instructions and references that you fully respect and comply with. Continuous training and monitoring of performance against these standards is essential if you are to remain in a stable ZD environment. Any changes to standards must come from the quality area and be fully trained and verified with the employees to which they apply.
- Development of personnel – there are many areas to consider when developing people. Target must be to employ effective teams and people. Skills matrices are to be developed and training plans fit with these needs, with a focus on ensure that we always have enough competence in all areas to deliver ZD products. Assessment should be ongoing (at least annually) to en-sure the core skill competences and no gaps appear in knowledge base.
- Employee motivation – each employee needs to have a certain amount of ‘knowledge hunger’ within them, otherwise expressed as the wish to learn and develop. The local management need to ensure that the workplace is one where the acquisition of knowledge and growth is encouraged and realised. WCA should be used as an indicator to measure the team motivation and ZD awards should be presented to the channel to recognise their achievement when milestones are reached. Local publicity media should announce the ‘good news’ when these milestone targets are reached and the team rewarded locally to celebrate their achievement.

There are 4 factors which then facilitate acquisition of knowledge and skills. These are:

- **Environment** – what the workplace is like and whether it is considered to be a good place to work. How empowered the employee feels by their surroundings will contribute to how quickly (or whether at all) they want to develop.
- **Experience** – the things that happen to us shape the way in which we learn. It is important to make the learning and growing experience a fun and yet challenging one, with clear benefits for both the employee and company to be seen. Doing the right things right is the core ingredient of Business Excellence in order to achieve ZD.
- **Personality** – each of us is unique and we all respond differently to challenging situations. Some feel the need to grow continuously and acquire knowledge. Others feel scared and withdrawn by the prospect of new challenges and prefer to avoid change. The team is what ultimately needs to win and therefore it is the team that needs to develop and grow which means we need to understand and respect our colleagues and peers.
- **Motivation** – ultimately the employee is the one who has to feel the need to develop his/her competences. Without this need the growth will not be natural and any skills or knowledge learned could be lost soon after-wards. To this end, it is imperative that employees feel motivated by the challenges in the areas in which they work. A certain amount of desire for success is needed to achieve ZD.

Communication within channel and operations

Each channel should have a recognised place where information can be communicated from the management.

Typical information that should be communicated includes any NCCs and their root cause analysis, SLR, efficiency and process operation flows. This has to be sup-ported by regular communication between the channel and all operative levels in a factory to ensure the correct understanding and agreement on targets.

Zero Defect understanding

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Everyone in the factory needs to understand what ZD is really about and the conditions necessary to make it happen.

To improve defect prevention, management must provide the necessary means for employees to ensure that the relevant controls are in place the channel environment. The three key points from the management that need to be assured are:

- the employees know what they are supposed to be doing
- the employees know what they are actually doing
- verification that both of the above points are true

If the above is achieved then it can be said that the channel are doing the ‘right things right’.

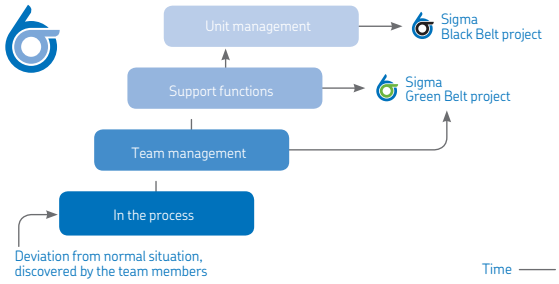
Ergonomic factors within the working environment should also be considered in terms of stretch goals for improvement.

Employees must constructively use the means provided by management to help prevent defects and seek help from their supervisors when and as needed. Employees are responsible for making suggestions or proposals for improvements, and will be encouraged to do so more of-ten if the workplace is one where their participation is encouraged and their opinions sought. This is indeed in line with the Ewellix values high ethics, empowerment, open-ness and teamwork. When employees discover a problem and cannot find a solution they need to seek management’s assistance via a suitable escalation process.

Quality system knowledge

Adequate knowledge of the Quality Management System shall be available and provided in the operations on all levels. This includes access to local procedures and the ability to demonstrate such knowledge. Procedures need to be followed and evidence of such is to be found inside documents relating to APQP+, PPAP and engineering changes. Each employee should understand the relation-ships between the procedures, control plan, work instructions, Process FMEA, etc. It is of the utmost importance that each employee knows and understands what to do in the event of non-conforming product being dis-covered and what reaction plans are to be put in place. Without this key point the ZD ethos will be lost.

Ewellix competency development model



The Ewellix escalation process.

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Zero Defect risk analysis

Process and Technology		Human Factors		Sourcing and external factors
The right process and technology	**The right support and service processes**	**The right people**	**The right organisation and policies**	**The right sourcing**
Green flow according to ZD handbook	Handling of scrap (instructions available and followed)	Competence in the job multiskilling, training programmes, mapping, etc)	External transport (product protection / packaging)	Agreement on drawing and specifications
SWC according to ZD handbook	Handling of rework (instructions available and followed)	Communication within channel and between operations ZD understanding available (employees, management)	Product / process specifications (available, known, accessible)	Identifications of critical parameters
Machine reliability (outliers)	Transport systems and buffers (handling damage, buffers, dirt, etc)	Q-System knowledge available (Engineering Change, APQP+, PPAP, etc)	NCC (supplier) handling / decision making (8D, feedback,	Capability of critical parameters
Process capability (Cpk > 1.33)	Identification of material (incoming parts, scrap, component identification, etc)		Black Channel concept)	Product approval (PPAP)
Measuring equipment reliability (outliers)	Specific requirements made available and visualised (on drawing, etc)		Prevention of reoccurance	Definition of supplier process route (rolling components)
Measuring equipment capability (%r&R < 10%)	Calibration system in place and maintained		Improvements carried over to other channels	Handling complaints
100% inspection / poka yoke for outliers	Resetting (defective parts passing)		Systematic communication of goals and results (employees, management)	Supplier performance follow-up (quality and delivery)
Ergonomic workplace (light, info available. orderliness, etc.)	Breakdowns secured (coolant, electricity, air-pressure, filters, temperature, etc)		Cost of quality knowledge available	Approval of manufacturing tools
Cleanliness (general level, 5S inplace, etc)	Hidden factor analysis executed		Channel leadership and clear responsibilities	Purchasing order and Quality
Tools according to specifications and approved	FIFO in place		ODR / TPM in place	Agreement
	Process FMEA up to date and communicated		Model control plan followed	Supply ZD plan
	Continuous improvement programme in place			
	Handling of scrap (instructions available and followed)			

The above picture represents the house of ZD Quality for a particular channel. All pillars are currently green but turn yellow and red depending upon the findings of the ZD audit.

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The ZD risk assessment (ZD audit) shall be performed at least annually by Quality Assurance of the respective factory. The audit should be performed after important events such as channel relocation or upgrades, or at any major engineering change. The risk assessment may be combined with the quality system audit performed on the manufacturing process. Re-auditing is necessary once major deviations (those coloured red in the ZD risk audit sheet) are corrected. The audit results shall be displayed close to the channel. Channels having a bad history of complaints (considered to be black channels according to the Ewellix definition) require a ZD audit to be performed. The result of this audit shall be part of management review and shall be followed-up on a suitable frequency until all points are closed out.

The output from the ZD audit is represented by a view which can be considered to represent a house of ZD quality. This is shown in the diagram overleaf.

The audit examines very closely the 5 pillars which have already been discussed in this handbook, but are:

- the right sourcing interfaces
- the right process and technology
- the right service and support systems
- the right organisation and methods
- the right people

The pillars all start as green, representing a ZD condition. As issues are found the pillars turn yellow and if the findings become severe enough, eventually red. The red signifies that the house is ‘on fire’ and that immediate corrective action is required to bring the house (or channel) back to a state of normality.

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Glossary

The glossary aims to explain in brief some of the terms used in creating this handbook.

Benchmarking

Comparing products and/or processes to a known standard considered to be the best, in order to evaluate and improve the performance. An internal benchmarking process consists of finding a process within Ewellix that is superior in one or more particular features, then studying it, and gathering ideas for your own operation in that area. It can sometimes be helpful to benchmark similar areas in different factories, e.g. soft turning, to see what is good and what is not so good. This forms part of the continuous improvement process.

Best practice

This term is typically used in the context of multi- location firms that have similar processes (such as Ewellix) in many locations. Normally this phrase is associated with benchmarking as it is normal to compare your own practise to that which is considered to be the best. In this way, the logic then gives that you will know which areas (black channels) need to be improved.

Corrective action report (CAR)

This forms an essential part of the Ewellix TER process and is used to describe the actual problem as found and the required actions needed to correct the situation.

Cause and effect diagram

A graphical tool that is used as a brainstorming approach for identifying the root causes of a problem. The diagram illustrates the relationship between several possible contributors and their likely effect. This tool is referred to by several alternative names such as; Ishikawa diagram and fishbone diagram.

Customer satisfaction

Customer satisfaction has become somewhat of a ‘cli-ché’, but if we examine it within a ZD context the phrase is better understood. A customer is a person (or part of an organisation) who buys something from you and with whom you develop a relationship. Satisfaction is achieved when the customer is free of doubt, suspicion, or uncertainty about the product or service they expect to receive. Satisfaction assumes that the product or service fulfils the customers needs and meets their required standards.

Defect

A defect is a product, process or service that does not meet the agreed needs or requirements of the customer. This could be a parameter which is outside the agreed specification or it could be a product that arrives 2 days later than agreed.

Delivery error report (DER)

These are complaints that are usually caused by the warehouse, logistics chain or by the factory. They include late deliveries, incorrect quantities, incorrect products, incorrect delivery mode or address, incorrect or missing labelling on transportation packaging, incorrect product packaging and defective product packaging. Complaints of this nature shall be formally documented in the relevant systems and corrective / preventive actions taken as necessary.

DMAIC

An improvement strategy used when performing Ewellix Six Sigma projects, and an acronym for define-measure-analyse-improve-control.

Design of experiments (DOE)

DOE is a systematic approach to the investigation of a system or process. A series of experiments are designed in which planned changes are made to the input variables of a process or system. The effects of these changes on a predefined output are then analysed. DOE is important as a way of maximising information gained while minimising resources and typically reduces the amount of testing that is required to assess many inputs and their

effects on the output.

Engineering change management (ECM)

Changes to products and / or processes shall be formally documented and the correct level of approvals shall be sought, where required, prior to the implementation of the change. The Ewellix database for change management shall be utilised to document both internal and external changes and the correct level of customer involvement shall take place on all occasions where changes are necessary. Customer specific requirements shall be respected with regard to each individual change and its particular circumstances.

Failure mode and effects analysis (FMEA)

FMEA is an analytical approach to quantify potential weaknesses (or risks) in products and processes. The aim is to define how a product or process could fail and then to either try and reduce the risk of failure or eliminate it entirely.

Five4U

This is the generic Ewellix defined improvement cycle. The five step DMAIC process will help us to have a general and standardised way to improve within Ewellix; to solve our deviations and to improve with structure; to achieve team based outcome to have a better communication and track the status with the support chain; to focus on the control phase and to achieve sustainable results (keep the problems from coming back or to anchor the improved normal situation).

Gap analysis

A term used to compare a current state and a target future state, and the work required to move between the two. Gap analysis enables us to set goals for improving processes and to develop strategies for improvement.

Green flow coverage (GFC)

Coverage of the production flow in critically identified areas (typically over flexlink) to avoid mixing known good components with potentially bad ones.

Hidden factor analysis (HFA)

A systematic way of uncovering process paths which are not normally obvious, as they happen infrequently, and yet pose the greatest risk to manufacturing of making an error. The HFA aims to map these additionally identified paths and ensure they are given consideration when constructing Process FMEA documentation.

Large size sample audit (LSSA)

A visual examination made on a large number of finished products or components that are in delivery condition, to assess the degree of defects not detected during the normal inspection, verification or process control operation. LSSA should be carried out for each manufacturing channel according to a local documented procedure which defines the characteristics to be inspected, the sample size, the frequency of inspection and the method of collection, inspection parameters and the level of required reporting.

Layered Process Audits (LPA)

A structured audit system which involves multiple layers of factory management participating in the local process audit schedule. This approach ensures the full commitment of the management team in fixing both short, medium and long term process deficiencies.

Non-conformance complaint (NCC)

Technical complaint that is received from an external customer, deriving from deficiencies in the manufacturing process.

Non-quality cost (NQC)

A summation of those costs necessary in fixing after the event problems due to poor quality that could have been avoided. Typically this cost will include scrap, losses, re-work, product sorting, customer complaint charges (including travel and expenses) and certified inspection.

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Operator driven reliability (ODR)

Operator involvement in improving the machine and equipment efficiency.

Production part approval process (PPAP)

PPAP is used (predominantly in automotive businesses) to establish confidence in component suppliers and their production processes by demonstrating that: all customer engineering design records and specification requirements are properly understood by the supplier, and that the process has the potential to produce products consistently meeting these requirements during an actual production run at the quoted production rate. The term PPAP is very automotive in its origins. Equivalent considerations from other industries are FAI (first article inspec-tion) and ISIR (initial sample inspection report).

Pareto analysis

This is also known as the “80-20 rule”, which is a representation of the relative importance of the process causes or defects based on the rule of thumb that roughly 80% of all problems result from about 20% of the causes. Used to separate the vital few from the trivial many.

Process capability

This is the total range of inherent variation in a stable process and can be determined using the data from control charts. The control chart needs to indicate stability before capability calculations can be made. Histograms are to be used to examine the distribution pattern of individual values and verify a Normal distribution. When analysis indicates a stable process and a Normal distribution, the indices of Cp/Cpk and Pp/Ppk should be calculated. If analysis indicates a non-normal distribution, advanced statistical tools (or PPM analysis) are required to determine capability. If control charts show the pro-cess to be unstable, only the Pp/Ppk indices can be calculated.

Performance Standard (PS)

This is what Ewellix considers to represent the cost of manufacturing the product. PS is calculated and fixed for a financial year and therefore does not accurately detail the exact cost for each part type, nor does it include any costs of doing business, e.g. sales and administrative costs, internal mark-ups, taxes, etc.

Root cause analysis

The basic concept of root cause analysis is to investigate the possible causes of a known problem.

Scrap without compromise (SWC)

SWC defines how scrap components should be handled inside the manufacturing channel to avoid mixing them with good quality parts and subsequently delivering them to the final customer. The focus of SWC is on parts rejected from automatic measuring devices and using some common sense methodologies to prevent mixing them with parts accepted. This concept is heavily linked to the GFC already discussed.

Sales error report (SER)

These are complaints that are usually caused by Sales or Customer Service and are typically system, invoice or despatch errors which cause incorrect quantities, incorrect delivery dates, incorrect products, incorrect pricing or incorrect shipment details. These complaints are with respect to what has previously been agreed or promised to the customer.

Ewellix Six Sigma projects (Black Belt or Green Belt)

Improvement projects, following the DMAIC roadmap.

SLR

This acronym represents scrap, losses and rework. It is used to assess the level of failure (waste) of the manufacturing process and systems in converting components into conforming products to be sold to the customer.

SQA function/SEA function

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Supplier quality assurance (SQA) is the old name for the newer function: Supplier Excellence Assurance (SEA). This role belongs to Group Purchasing. Supplier Excellence is split by either commodity (SEC) or by region

(SER). Their main tasks are approving suppliers, performing audits to support supplier approval and driving improvement projects across the purchasing function.

5S

5S is a reference to five Japanese words that detail the improvement process required in a production channel – Sort, Set in order, Shine, Standardise and Sustain.

Technical error report (TER)

Technical complaints are generally caused by errors in product manufacture, design or engineering and include both zero hour failures and field failures. A zero hour failure is regarded inside Ewellix as a NCC (non-conformance complaint) and is defined as occurring before a product enters service. This is the point at which the product is used in the intended application by the end user. NCCs typically include out of conformance specifications (where the product does not meet the requirements as defined on the drawing records), mounting failures, end of line testing failures and commissioning failures. Field failures are regarded inside Ewellix as NPC (non-performance complaints) and are defined as failures occurring after a product has entered use in the intended application by the end user. NPC can be subject to warranty claims by customers and this would depend on the applicable terms and conditions of sale with regard to how long the warranty period lasts for and if the failure occurred within that timeframe.

Total preventive maintenance (TPM)

TPM is a production management approach that places the responsibility for routine maintenance on the workers who operate the machinery, rather than employing separate maintenance personnel for that function. The aim is to improve uptime of the machinery while at the same time improving some of the more basic maintenance functions, like oiling and greasing, etc.