BUREAU VERITAS

Auditing to IECEx OD 005 :

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Held in Buxton

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For the benefit of business and people

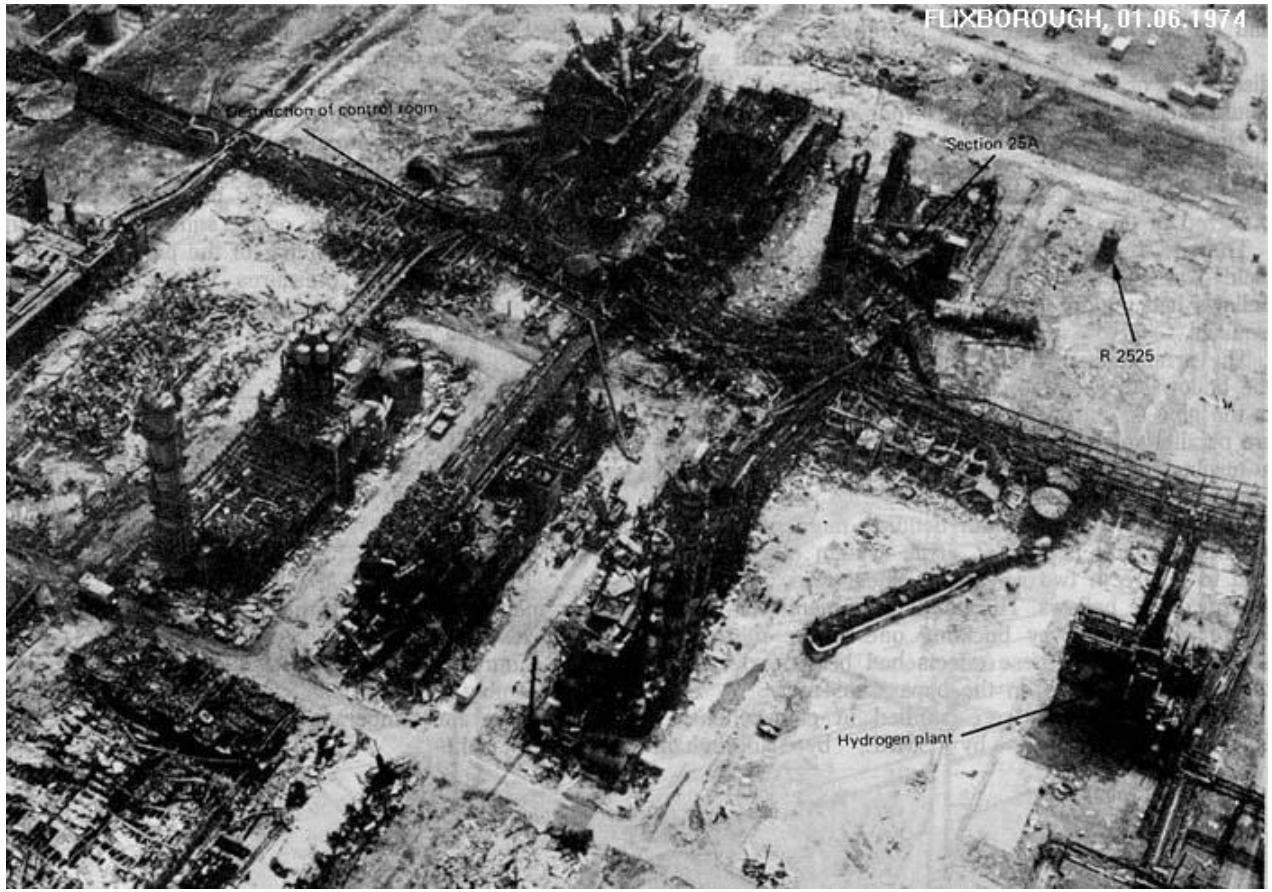
INTRODUCTION

WHY AUDITING FACTORY?

INTRODUCTION

TO PREVENT…

FLIXBOROUGH UK 1974



INTRODUCTION

TO GIVE CONFIDENCE TO:

Manufacturers and Members of the Scheme!

INTRODUCTION

And To Regulatory Bodies

Local Authorities,…

INTRODUCTION

HOW?

In Preventing Product to drift away from its Ex Specifications

INTRODUCTION

HOW?

In applying IECEX auditing rules in a professional way

INTRODUCTION

Professional?

Auditor has the following knowledge :

Ex Type of protection
Ex testing

Sound knowledge in manufaturing
e.g.: molding, injection, machining,...

Auditing skill

Good Understanding of its responsibility

INTRODUCTION

Auditing under IECEx OD 005 is all about prevention of drifts in production.

It is all about decreasing liabilities of the players.

It is all about maitaining an EX product in its Ex certified specifications

It does allow space for controlled changes

I

Short Introduction to ISO 9001-2000

It is a QUALITY MANAGEMENT SYSTEM

I

Introduction to ISO 9001-2000

☞It can be used by external parties to assess the organization's ability to contribute meeting customer, regulatory requirements

and the organization's own requirements.

I

Introduction to ISO 9001-2000

It is a QUALITY MANAGEMENT SYSTEM

☞**Based on PROCESS APPROACH**

I

Introduction to ISO 9001-2000

A process is made of any linked activities

managed in order to enable the

transformation of inputs in outputs.

Often output from one process directly

forms the input to the next

I

Introduction to ISO 9001-2000

☞**5 Processes have been identified**

I

Introduction to ISO 9001-2000

- Management Responsibility
- Quality Management System
- Resource Management
- Production/Product Issues

I

Introduction to ISO 9001-2000

☞**ISO 9001-2000 requirements**

are complementary

to requirements for product

I

Introduction to ISO 9001-2000

☞**ISO 9001-2000 results**

from the merging of former

ISO 9001-1994

ISO 9002-1994

ISO 9003-1994

II

IECEX OD 005 and EN 13980

IECEx OD 005 and EN-13980-2002

Auditing documents

Set out IECEx and Ex EU Schemes

requirements for Manufacturers

Quality Systems

II

IECEX OD 005 and EN 13980

Both documents have the same structure.

And

For practical reasons this structure is aligned on the ISO 9001-2000 structure;

BUT THIS MAY BE MISLEADING!

II

IECEX OD 005 and EN 13980

Both IECEX OD 005 and EN 13980

Are Ex Product Production oriented

III

ISO 9001-2000, IECEX OD 005 and EN 13980

Within the 5 processes identified in

ISO 9001-2000,

emphasis is given to

Production and Product parameters

that may affect the integrity of Ex Product

III

ISO 9001-2000, IECEX OD 005 and EN 13980

Therefore both use ISO 9001-2000

to give a quality frame* that is normally not assessed if the manufacturer holds a valid ISO 9001-2000 certificate issued by a recognized body.

***(related to internal processes)**

III

ISO 9001-2000, IECEX OD 005 and EN 13980

This approach brings the following benefit :

It is an opportunity to deal with actual manufacturing in relation with Ex features of the manufactured product.

III

ISO 9001-2000, IECEX OD 005 and EN 13980

ISO 9001-2000

is good for the Manufacturer's image

Contribute to meet Customer expectations

by improving company processes

III

ISO 9001-2000, IECEX OD 005 and EN 13980

ISO 9001-2000

FOCUSES MAINLY ON PROCESSES

(organization)

III

ISO 9001-2000, IECEX OD 005 and EN 13980

Both IECEX OD 005 and EN 13980

Focus on Content of Processes

more than on processes as such

IV

ISO 9001-2000, IECEX OD 005 and EN 13980

IECEX OD 005 and EN 13980

Focus

on improved control of changes

in production in relation

to Ex Features

IV

ISO 9001-2000, IECEX OD 005 and EN 13980

IECEX OD 005 and EN 13980

Contribute to maintain safety

of produced Ex product

over time

IV

ISO 9001-2000, IECEX OD 005 and EN 13980

IECEX OD 005 and EN 13980

Properly conducted assessment under one of the above documents contribute actually to decrease both

the liability of the manufacturer

and of the auditing company

IV

IECEx OD 005 versus ISO 9001-2000

Similarities :

Both systems are Voluntary

IV

IECEx OD 005 versus ISO 9001-2000

Similarities :

Structure of document is identical

Processes number is identical

Processes are similar

V

IECEx OD 005 versus ISO 9001-2000

Differences :

IECEx OD 005 does not preclude the use, by a Manufacturer, of other quality systems that are compatible with the objectives of ISO 9001-2000

V

IECEx OD 005 versus ISO 9001-2000

Differences :

IECEx OD 005 have 23 additional requirements to embrace the "good" manufacturing practices appropriate to Ex Product

V

IECEx OD 005 versus ISO 9001-2000

Extent of the Assessment

↓

Points to be checked :

1) HAS THE MANUFACTURER A VALID ISO 9001-2001?

2) HAS HE A VALID SCOPE?

V

IECEx OD 005 versus ISO 9001-2000

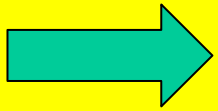
YES

Assessment is limited to Ex Requirements

V

IECEx OD 005 versus ISO 9001-2000

NO



Assessment is extended to ISO provisions

V

IECEx OD 005 versus ISO 9001-2000

Differences :

IECEx OD 005 have Annexe A and B

Draw the attention of the Manufacturer on some key technical points to be delt with during production

V

IECEx OD 005 versus ISO 9001-2000

SOME MAJOR Ex REQUIREMENTS :

V

IECEx OD 005 versus ISO 9001-2000

§ 5.4.2 Ex Requirements, provision that :

"a manufacturer shall facilitate an arrangement whereby the ExCB may audit aspects of the suppliers operations that affect the type of protection" e.g : casting, machining

V

IECEx OD 005 versus ISO 9001-2000

§ 5.5.1 Ex Requirements develop significantly the Responsibility and Authority requested for "good" manufacturing of Ex product.

It recommends that (an) *authorised person* (s) to be appointed.

V

IECEx OD 005 versus ISO 9001-2000

§ 5.6 Commitment of Management with regards to

of Ex Product is emphasized

V

IECEx OD 005 versus ISO 9001-2000

§ 7.4.1 Purchasing Process has been significantly highlighted.

Deals in detail on how to select, qualify a *supplier of product, process or service that can affect the product's compliance with the ExTR.*

V

IECEx OD 005 versus ISO 9001-2000

Proposes means of evaluation

Deal with providers of calibration

Attention is drawn on differences between "review"

and "re-evaluation" of suppliers

V

IECEx OD 005 versus ISO 9001-2000

§ 7.4.3 Verification of purchased Product

has been extensively strengthened.

V

Case Fan supplier

Data : Do you check Incoming fan from your supplier?

No, I receive, for this fan made of Polyamide by my supplier, a declaration of conformity. That's largely sufficient, I know this supplier for 15 years.

Is this response acceptable?

V

Case Fan supplier

Reality : Upon checking, it appeared that the declaration said simply : I hereby declare to comply to the specification of the manufacturer and was endorsed by the supplier.

Looks good for a possible legal action….against the supplier

V

Case Fan supplier

point actually checked :

What specifications were actually provided?

When initially? Regularly updated and send to supplier?

Update acknowledged by supplier?

What is specified in the certification file?

V

Case Fan supplier

Outcome : Specifications to supplier consisted of only the mechanical dimension through a drawing dated : year of audit – 5 years.

Polymer not specified on drawing although specified in certified specifications, requested in fact only by phone.

V

Case Fan supplier

(Dark) layer to evacuate possible charges not defined to supplier, although a measurement of its aptitude has been made by the test house .

In this situation declaration of the supplier is clearly in favor of the supplier.

This may endanger the manufacturer and possibly customers

V

Case Fan supplier

as in case of a prosecution, after an accident the Court may put on the sole shoulder of the manufacturer a financial responsibility he may not stand.

V

Case A small Ex shaft machined externally

Data : A small Ex shaft on a rotary switch is received by the manufacturer from an external supplier

Question how do you check delivery 100%?

“I do only visual check the actual Ex dimension are measured by my supplier who supplies me with a declaration of conformity”

V

Case A small Ex shaft machined externally

Upon auditing it appeared that specifications

were well transmitted (with each orders), well updated,

acknowledgement from supplier received and declaration of

conformity attached to each delivery.

Situation looks better!!!! Few questions later…

V

Case A small Ex shaft machined externally

Has the supplier a sampling plan that <u>you</u> have agreed?

“HuH…”

Any dimension check on actual delivery? “No”

Upon checking if the supplier was regularly audited the response was “until he failed there is no maintenance audit”.

What failure? “Delivery time”.

V

Case A small Ex shaft machined externally

"But you know the supplier has only automated machine tools"

What happens if your can't supply the delivery with it's usual machine ?

Actual measurements done during the assessment on a random basis showed that 20 % of the measurements were out of the required specifications.

V

Case A small Ex shaft machined externally

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Clearly although the situation is better the manufacturer has not really full control of its supplier and so the prevention aspects are not delt appropriately

V

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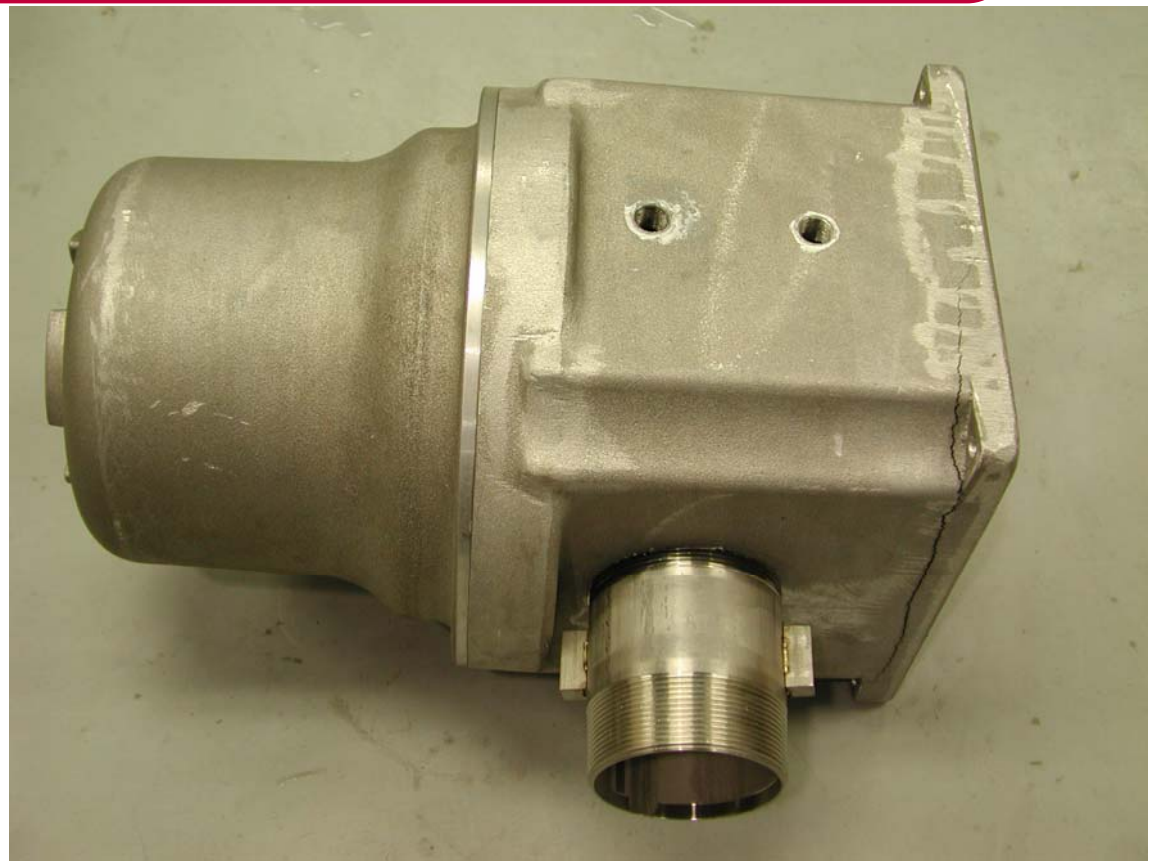
V

Equipment that failed Ex Routine test



V

Aluminium casted “d” box case

Manufacturer has one supplier for aluminium casted “d” boxes :

Supplier, serial number, period of production is identified on the product with a stamp.

Product is exempted of performing routine pressure test because of optimized construction structure

V

Aluminium casted “d” box case

Should the auditor be happy because traceability is visible?

During the assessment of the maintenance of documentation of the related drawings §4.3

It appeared that this stamp was never mentionned on the drawings nor requested

As the stamp was dep and place in a n area where the thickness was significantly affected a overpressure test was requested.

Resulting in a nice leak at the very place of the stamp at apressure that appeared later to be only 1.5 the Max P

V

Aluminium casted “d” box case

Reality :

Although the supplier was pleasing the manufacturer because of this traceability, this changes was made out of the control of the manufacturer as no approved request for change has been issued and approved by a competent person

V

IECEx OD 005 versus ISO 9001-2000

§8.3 Control of non Conforming Product is significantly reinforced, relation with the different possible ExCBs involved is clarified.

An important issue relating to product difficult to trace is adressed.

V

IECEx OD 005 versus ISO 9001-2000

"Concessions that take the product outside the designed as defined in the ExTR and technical documentation are not permitted"

V

Case of Uncontrolled change in Color

Data : Upon visiting the storage area of a manufacturer supplying a ventilation system, some of the Ex equipment were Blue and some Yellow flashy.

Why this change? "For marketing reason, we participate to an exhibition and yellow would certainly be more attractive"

V

Case of Uncontrolled change in Color

A look to the certified specifications showed that the color was a part of the requirements : Because the ventilation system was using is own flow to cool down a risk for ESD was anticipated. Therefore the type of color generating no ESD was made and certified.

The modification for change did not follow the normal path as it was view by marketing as a cosmetic request

V

Case of Uncontrolled change in Color

Clearly the new color was of a nature that could create ESD risk.

Therefore, it was requested to have this point checked.

As a result this color was forbidden and the circuit of modification request be modified to include all requestors.

V

Case of Uncontrolled change on “d”product

Data : Audit is conducted on a “d” small motor production

The production to be audited is a “d” motor with one shaft coming out of one flange.

Upon checking the related drawings made clear that an other shaft was now on the on the flange.

Question why this was not consider as a major changes?

V

Case of Uncontrolled change on “d”product

Answer : “this change was considered as minor for reason of symmetry”

Therefore the it was requested this product to be certified the changes as an amendment to the initial cerificate..

The reality is : The first non transmission test led to a failure.

The manufacturer was requested to implement §8.8 on non conforming product.

It tooks 8 months for him to withdraw the product on the market.

V

Conclusion

Ex Auditing

is the key for a long lasting credibility

It shall be performed seriously by all the players

V

THANK YOU!

VII

PIPER ALPHA