TGA THERAPEUTIC GOODS ADMINISTRATION

Manufacturer Assessment Section

ISO 13485:1996 Quality System Audit Checklist

Medical Vision Australia

Organisation Name:

Poly Implants Protheses

Conformity Assessment Audit date(s):

17-19 November 2003.

Quality System Requirement	Document Review	Audit observations
4.1 Management responsibility		
4.1.1 Quality policy The suppliers management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organisational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organisation.	**Is quality policy documented?**	In Manual + reiterated in yearly letter to staff (importance)
	Is the policy relevant and appropriate?	→ A.L.
	Is the policy communicated and understood by all staff?	→ A letter is sent out called "Declaration de la Direction" once a year.
4.1.2 Organisation **4.1.2.1 Responsibility and authority** The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organisational freedom and authority to: a) initiate action to prevent the occurrence of any non conformities relating to the product, process and quality	**How are the responsibilities and authorities defined?**	Organisation Chart) - Index A Communicated to all staff once a year by letter (with pay) + put on staff bulletin board → H.R. keeps records called "(A.L.)"
	Are an organisational chart and position descriptions for head of production and head of quality function available?	Yes SQ1/01 OR6 002 Index : A. → Request info from customers

system; b) identify and record any problems relating to the product, process and quality system; c) initiate, recommend or provide solutions through designated channels; d) verify the implementation of solutions; e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.	**Are they appropriate?**	→ (Yes) - have Complaint Dept.
4.1.2.2 Resources The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.		- identify it at the yearly letter time plus meetings every 3 months to establish resources for new products. - this letter reiterates the importance of keeping trained staff.
4.1.2.3 Management Representative The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and	**Who is the Management Representative?** **Are these requirements addressed in the job description?**	Mr. Burel (ie. Quality Director). → will check on HR — checked that MR Burel are part of his duties. On leads.

b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system. NOTE 5 The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system	**What is the evidence that these requirements have been effectively met?**	→ part of Management review. - Various Department have to report to Management review.
4.1.2.4 Management review The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the suppliers stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).	**Is there a formal periodic review of the quality system and how is it done?** **Are the intervals between reviews appropriate?** **Do the reviews meet the requirements?** **Are records of the reviews maintained?**	- review meetings held every 3 mths. in SA → [depends on complaints] → *. ie. everyone i.d. applicable boxes on organisational chart. → All key personnel involved with Management review → Yes, records easily retrieved. ↳ & extensive; identified resources reqd to meet each objective set, the progress, action met by whom ↳ showed eg. clinical trial progress for 2003 → 2000 PX

4.2 Quality system		
4.2.1 General The supplier shall establish document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system. NOTE 6 Guidance on quality manuals is given in ISO 10013. *The supplier shall establish and document the specified requirements.* *Note: If this Standard is used for compliance with regulatory requirements, the relevant regulatory requirements of the regulations should be included in the specified requirements.*	**Has a quality manual been prepared?** **Does the quality manual address the requirements of the standard?** **Does the quality manual include or reference the QS procedures and outline the structure of the documentation of the QS system?**	Yes - provided prior + up to date. SQ1/02 MAQ 001 B Yes - to 13485 1996 & moving to 2003. → on p. 5
4.2.2 Quality system procedures The supplier shall a) prepare documented procedures consistent with the requirements of this International	**Are there documented procedures for each of the elements of the quality standard?**	✓ Flow chart & associated DOCs -

Standard and the suppliers stated quality policy, and b) effectively implement the quality system and its documented procedures. For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity. NOTE 7 Documented procedures may make reference to work instructions that define how an activity is performed. *The supplier shall establish and maintain a file(Device Master File) containing documents defining the product specifications, including complete manufacturing and quality assurance specifications for each type/model of medical device, or referring to the location of this information (see also 4.5.2 and 4.16).*	**Are the quality system procedures implemented effectively?** -Subjective **Is a Device Master File for each product available?**	Place seems to be working well, staff knew what they were doing A.L. says its really the flow charts - SQ1/02 SYN 305 +(one for Textured). NOT Technical File. Silicone gel Implants SQ1/02 DOT 202 Yes - Each product line has a DMF with (called for) containing all relevant docs - except called Tech File.
4.2.3 Quality planning The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other	**How are the requirements for quality documented?**	+ Flow chart is also the Quality plan. + resource planning

requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts: a) the preparation of quality plans; b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality; c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation; d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation; e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed		basically Flow chart + resource planning

f) the identification of suitable verification at appropriate stages in the realisation of product; g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element; h) the identification and preparation of quality records (see 4.16). NOTE 8 The quality plans referred to [see 4.2.3a)] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.		

4.3 Contract review		
4.3.1 General The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities. **4.3.2 Review** Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that: a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance; b) any differences between the contract or order requirements and those in the tender are resolved; c) the supplier has the capability to meet the contract or order requirements.	**Are there documented procedures for contract review?**	

4.3.3 Amendment to a contract The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organisation . **4.3.4 Records** Records of contract reviews shall be maintained (see 4.1 6). NOTE 9 Channels for communication and interfaces with the customer's organisation in these contract matters should be established.		

4.4 Design control (ISO 13485 only)

4.4.1 General

The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

Are there documented procedures for control of design activities?

SOD's SQ1/02 PCS 004 design + develop (process).
→ SQ1/04 PCD 001 : design control

4.4.2 Design and development planning

The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as the design evolves.

Select and review example(s) of design projects.

→ 1,1,1 + cethane → xylene – PR009 project.
in one of the envelopes
(ie: solvent)..

Was the project plan clearly documented?

{ – time / issue
– + ease. }

How were changes to the plan controlled?

→ SQ1/04 FOR 400 : there is a project monitoring form + one for design review.

4.4.3 Organisational and technical interfaces

Organisational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted and regularly reviewed.

Were the interelationships of different groups involved in design activities defined?

– yes in SQ1/04 FOR 405 PCD 004 : (chart #)
↳ describes form for these inter-relationship

4.4.4 Design input Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements. Design input shall take into consideration the results of any contract review activities. *The supplier shall identify requirements that are related to the safety of the medical device and shall include such requirements as design input data.*	**How did the design groups document and review information?**	– Risk analysis – Review to validate the risk analysis + research of selection of suppliers ↓ – included in documentation anyway even though the xylene dispersion was the same.
	Was the safety of the device included as an input into design?	– Yes C.1.2. – biol. safety 1st tier + 2nd tier & material tests & extraction tests ON all components of shell + patches + glues.] archive data at end included in folder
4.4.5 Design output Design output shall be documented and expressed in terms that can be verified and validated against design input requirements. Design output shall: a) meet the design input requirements b) contain or make reference to acceptance	**How was design output documented?** **Was the output verified against input?**	– Specs for new products clearly identified + controlled. → Output data documented for each input spec. FOR PIP (specs form ↳ identified in Table for Annex H (biol. safety data) & Annex XXX.Y for material testing.

criteria; c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g. operating storage, handling, maintenance and disposal requirements). Design output documents shall be reviewed before release. **4.4.6 Design review** At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16). **4.4.7 Design verification** At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4. 16).	**How were design output documents reviewed before release?** **Were reviews of the design project carried out at appropriate intervals?** **Were appropriate personnel involved?** **Were the reviews documented?** **Was design verification carried out and recorded?**	- identified in initial design input - docs were reviewed + signed off on index page - → risk analysis (to EN 1441) conducted for (c) - mainly changes re mech. tests, biol. safety, sterility, packaging, storage, Controlled by PR/009 (?). - date that new product was 'accepted' for release Yes - there were 2/3 reviews initially to see if project was on track The Prod. Manager, R+D people were involved in them (test + methodolog Doc + controlled. - The testing regime was to do all the tests for the old product + to test them again for any changes - all mech test performed.

The supplier shall document and maintain records (see 4.16) of all design verification activities including those where clinical investigation was involved.

NOTE 10 In addition to conducting design reviews (see 4.4.6), design verification may include activities such as

– performing alternative calculations,

– comparing the new design with a similar proven design, if available,

– undertaking tests and demonstrations, and

– reviewing the design stage documents before release.

4.4.8 Design validation

Design validation shall be performed to ensure that product conforms to defined user needs and/or requirements.

NOTES

11 Design validation follows successful design verification (see 4.4.7).

12 Validation is normally performed under defined operating conditions.

13 Validation is normally performed on the final product, but may be necessary in earlier stages prior to product

How was design validation carried out?

~~verification~~:
- review of validation data carried out at very end again to verify ~~out~~ all the stages.

- Currently doing Px trials (≥000 px enrolled) with thin material.

→ only viscosity slightly changed. mechanical tests/parameters same
- compared to previous design
in file – all tests as per specs +
yes, design ~~of~~ at each stage & at very end.

- By testing to specifications of device as established previously
- only diff. was viscosity ~~para~~ – established parameter

- Yes PR 00/109 K1. Includes summary + data for each of the validations of ~~para~~ tested.

→ 13. – Yes done on Dipping, Texturisatic plates, Laser (limited to id. etc) ~~some simple me~~

+ final product.

trenpase : dipping.

completion . 14 Multiple validations may be performed if there are different intended uses. **4.4.9 Design changes** All design changes and modifications shall be identified, documented, reviewed and approved by authorised personnel before their implementation. [-has there been a change in the closure patch from MED 2245 to MED b 6400 ↓ NO- misunderstanding by mech. eval. MED 2245 is glue .]	**Were design changes appropriately managed?** yes – at each stage + at end also after 1st production batches (3 batches).	→ 3 lots of each of the smooth, textured tested according to sampling plan } but 1 lot gel, 1 lot balm, 1 lot hydrogel → there is an implementation date set for when the change came into force + the changes were clearly i.d. ; documented, reviewed & approved by the rec. personel – all data validated + approved → equipment identified → For each model, the implementation date was documented

each lot has a Device History File with all parameters, specs and equipment identified .

[(Lot ~~22700~~ 27700)] – validation batches for change

Form XXX.Y

– production batches after changes of tce to xylene implemented were included in the design change file

4.5 Document and data control		Hannelore FONT
4.5.1 General The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings. NOTE 15 Documents and data can be in the form of any type of media, such as hard copy or electronic media.	**Are there documented procedures for document and data control?** stamp → P.I.P. AQ 1 * NC	Yes – every person identified in process has a green stamp that has the Department identified & the number assigned to them – they initial it & paper copies are stamped with red "COPIE" – however this red "COPIE" requirement does not seem to be in the docs SQ1/05 PCD 001 or SQ1/02 PCS 005 ... versions ... –Only Virginie can make + stamp Red "COPIES" but not → see above indicated as so in SOP. No control on who has copies – distn list
4.5.2 Document and data approval and issue The documents and data shall be reviewed and approved for adequacy by authorised personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents. This control shall ensure that:	**Who approves documents prior to issue?**	Reviewed by Quality Assurance Manager. – approved Quality Director/Manager – process for doing so in SOP – Master List identified c̄ current revision status. – Distribution list referred to in SQ1/05 with who is supposed to have SOP – ~~HF~~ showed me 2 → ~~copys~~
a) the pertinent issues of appropriate documents are available at all locations where operations	**Are appropriate documents available at points of use?** photos	~~– see form~~. – there were photocopies of the packing docs in the Zdany room (black stamp) + One on door FKA 22 0/03 – red stamp but Stamp at approval was

essential to the effective functioning of the quality system are performed; b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified. *The supplier shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that specifications to which medical devices have been manufactured are available for at least the lifetime of the medical device as defined by the supplier (see 4.16).* **4.5.3 Document and data changes** Changes to documents and data shall be reviewed and approved by the same functions/organisations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organisations shall have access to pertinent background information upon which to base their review and approval.	**Were invalid or obsolete documents found in the workplace?** — copy yes — see prev. 2° picks : examine. **Were obsolete documents suitably identified?** — how identified **How long are obsolete documents retained for?** ↓ see above. ↓ SO Level 3 + 4 + 5 should be kept for longer than 15 years as lifetime of device is longer than 15 yrs	photos easily not visible. — yes — see previous page. — no red stamp "COPIE" or green approval stamp. — Ms. Font didn't know why there was a photocopy in packaging - stamped ē outdated for paper copy - QMS on computer system for outdated files is named "Archived" — renamed + archived to specific room (locked — Ms Font showed me on Plan). → approval for moving docs to "archive" is only by the Doc. control manager (Virginie) + only she has the computer authority to do so. People who are allowed to print them are on the database as being approved to do so - p. 7 "not managed documents" — sighted on document in French.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.		identifies – Sidebar, changes in the latest revision which staff are all aware of ~~HOWEVER doesn't appear as the~~ – in FAQ 050/05 this procedure is detailed (in French so this Foat translated + showed me) on p. 2/2 with vertical lines (they use WORD tracking changes in the comp-doc. Documentation in in both Eng. + French for each document

4.6 Purchasing		
4.6.1 General The supplier shall establish and maintain documented procedures to ensure that purchased product (see 3.1) conforms to specified requirements. **4.6.2 Evaluation of subcontractors** The supplier shall a) evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements; b) define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors; d) establish and maintain quality records of	**Are there documented procedures for purchasing and ensuring that purchased product conforms to specified requirements?** **How are subcontractors evaluated and selected?** **Is there periodic review of subcontractors once selected.** **Select and review records of evaluation/selection and ongoing controls of some subcontractors**	In area used – approved copies of SOP on wall – operator cfs what came in to what was ordered Lot# 28882 – old lot received for 5 months new lot 26892 ↓ they test sample of silicone when it's received initially for new Lot procedures → Green 'Acceptance' – received O.K. ↓ Q.C. has other stickers for acceptance + rejection prior to leaving quarantine 6400 A – in Quarantine (Part B) ↓ A.L. found A sticker on Part B / B " on Part A → Corrected on Spot

acceptable subcontractors (See 4.16).

4.6.3 Purchasing data

Purchasing documents shall contain data clearly describing the product ordered, including where applicable:

a) the type, class, grade or other precise identification;

b) the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;

c) the title, number and issue of the quality system standard to be applied.

The supplier shall review and approve purchasing documents for adequacy of the specified requirements prior to release.

To the extent required by the particular requirements for traceability in 4.8, the supplier

Warehouse : perhaps need airlock or cancel on doors to entry to Q.C. area.

Musil MED3 6300.

4442 + 4427 - M

sighted in Store MED6 6400 (G) ← version G.

→ there are "Receipt Quality" categories 10, 20, 30, 40 - higher numbers less contact = produc

so in purchasing it was also identified as G.

→ some product (20% conc) that has no stamp on it

(FSE 300/01 Inst)

sighted PCD-001 — the SOP that detailed what has needed

receipt of material.

→ PCD-003 (001 refers to 003) which details how it is to be sampled

some product does

shall retain copies (see 4.16) of relevant purchasing documents. **4.6.4 Verification of purchased product** **4.6.4.1 Supplier verification at subcontractor's premises** Where the supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents. **4.6.4.2 Customer verification of subcontracted product** Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor. Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.	→ N/A Purchasing ?. Check if it comes directly from Nusil or thru distributor.	→ Docs are retained in purchasing received paper copy ALSO on computer system Directly from Nusil Suppliers ~~are~~ ~~p~~ provide Class 10 (11, 12) products to ~~Nusil~~ P.I.P. requirements. 6300 – sighted + checked documents. – Raw Materials at Level 10 are audited by PIP every 2 years.

4.7 Control of customer-supplied product		
The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.6). Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.		• the testing for incoming goods occurs on (A+B) • xylene - ~~spec~~ rely on + testing of suppliers

- Don't seem to be able to easily track through if there is a problem ~~c~~something raw material being contaminated
- have to check each Lot's Device History Record. which are ~~J~~peg files
- replied they'd check each.

R+D: Mr Gaussic

1) verification

2) Supplier of xylene, heptane, ~~etc~~ Sigma etc - all chemicals are Class '10' - means suppliers are all accredited by relevant body to Standa and they ~~sign the~~ are contractually required to inform PIP of any changes to product

4.8 Product identification and traceability		
Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation. Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16). ***Particular requirement for all medical devices:*** *a) Identification* *The supplier shall establish and maintain procedures to ensure that medical devices received for refurbishing are identified and distinguished at all times from normal production.* ***b) Traceability*** *The supplier shall establish, document and maintain procedures for traceability. The*		- Drums of A+B – See p. 18 - Lot ID - see previous pg. - unique I.D. not on each diff delivery ~~lot~~ received from the one Lot NC - each received 'lot' from the 1 supplier batch does not get a different number

procedures shall define the extent of traceability and facilitate corrective and preventive action (see 4.14.2) ***Additional requirements for active implantable medical devices and implantable medical devices:*** *The extent of traceability shall include all components and materials used, and records of the environmental conditions (see 4.9B)d), when these could cause the medical device not to satisfy its specified requirements.* *The supplier shall require that its agents or distributors maintain records of the distribution of medical devices with regard to traceability and that such records are available for inspections.*		→ no lot # put on each incoming batch – ie identifying delivery lots. → b/c records of environ. conditions need to be included then each delivery lot needs its own I.d. even if it's the same batch of raw material.

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4.9 Process control		
The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following: a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality; b) use of suitable production, installation and servicing equipment, and a suitable working environment; c) compliance with reference standards/codes, quality plans and/or documented procedures; d) monitoring and control of suitable process parameters and product characteristics; e) the approval of processes and equipment, as appropriate; f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g.	~~environment~~ - holes in walls, unsealed benches exposed particle board.	Controlled conditions - doc - procedures available. → equipment suitable and a suitable working environment → do when it's appropriate → testing.

written standards, representative samples or illustrations); g) suitable maintenance of equipment to ensure continuing process capability. Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met. The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified. NOTE 16 Such processes requiring pre-qualification of their process capability are frequently referred to as special processes. Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see 4.16).		- done - sterilisation is a special process - process itself is when you can't test without destroying

Organisation Name: **Poly Implants Protheses**

Conformity Assessment Audit date(s): **17-19 November 2003.**

A) Personnel *The supplier shall establish, document and maintain requirements for health, cleanliness and clothing of personnel if contact between such personnel and product or environment could adversely affect the quality of product.* *B) Environmental control in manufacture* *For medical devices* *a) that are supplied sterile; or* *b) that are supplied non-sterile and intended for sterilization before use; or* *c) where the microbiological and/or particulate cleanliness or other environmental conditions are of significance in their use; or* *d) where the environmental conditions are of significance in their manufacture; the supplier shall establish and document requirements for the environment to which product is exposed.* *If appropriate, the environmental conditions shall be controlled and/or monitored.*	★Need to see SOP FME 300/02 FME 011/01 B ↓ check clean room. FME 501/01 FME/500/01 502/xx 951X! sighted on Tues ↓ copies in English provided to A.L. - the requirement for plate count agar (PCA) needs at 30°C to pick up bacteria and fungi had not been validated for demonstrate the recovery of low numbers of bacteria and fungi	→ Have requirements for staff working in clean room: SQ1/02 PCS 010 water is purified using a 2 carbon filter. ↓ Ca^{++} Mg^{++} filter ↓ filter 0.2 µ. ↓ UV. Water Essentially at least Grade 3, perhaps Grade 2. – dust rate – microbial – particulate matter – DOP – kinetics. – air flow – records. – "air treatment plants" Monitoring is an issue

C) Cleanliness of product *The supplier shall establish, document and maintain requirements for cleanliness of product if:* *a) product is cleaned by the supplier prior to sterilization and/or its use; or* *b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use; or* *c) product is supplied to be used non-sterile and its cleanliness is of significance in use; or* *d) process agents are to be removed from product during manufacture.* *If appropriate, product cleaned in accordance with a) or b) above need to be subject to the preceding particular requirements, i.e. A) Personnel and B) Environmental control in manufacture, prior to the cleaning procedure.* *D) Maintenance* *The supplier shall establish and document*	Yes — have	— washing in water — H_2O_2 used prior to packing — from data in Tech File — monitor it xylene residues — checked that showed it was lower than read

requirements for maintenance activities when such activities may affect product quality. *Records of such maintenance shall be kept (see 4.16).* *E) Installation* *If appropriate, the supplier shall establish and document both instructions and acceptance criteria for installing and checking the medical device.* *Records of installation and checking performed by the supplier or his authorized representative shall be retained (see 4.16).* *If the contract (see 4.3) allows installation other than by the supplier or his authorized representative, the supplier shall provide the purchaser with written instructions for installation and checking.* *F) Special processes* *The supplier shall ensure that the quality records of special processes (see 4.16 and note in 4.9 of EN ISO 9001 : 1994) identify:* *a) the work instruction used;*	what are these besides sterilization?	Environmental monitoring

b) the date the special process was performed; *c) the identity of the operator of the special process.* ***Additional requirement for sterile medical devices:*** *The supplier shall subject the medical devices to a validated sterilization process and record (see 4.16) all the control parameters of the sterilization process.*		- MXN provide certificate

4.10 Inspection and testing

4.10.1 General

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

FSE 300/01 for MED6 6400
→ protocols are TM 002 – clear
004 – 35-37
001 – 900–1200
006
007
009 → ILS
028 → inside

→ specs set.

4.10.2 Receiving inspection and testing

4.10.2.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures.

→ Quarantine requirements (yellow stickers) – each staff office has their own stamp.

Do not place diff Lot #s on each incoming delivery of the same batch from supplier

4.10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

* Sighted & in order + up to dated

→ test viscosity + dry extract on each incoming delivery

4.10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements. **4.10.3 In-process inspection and testing** The supplier shall: a) inspect and test the product as required by the quality plan and/or documented procedures; b) hold product until the required inspection and tests have been completed or necessary reports have teen received and verified, except when product is released under positive-recall procedures (see 4.10.2.3). Release under positive recall procedures shall not preclude the activities outlined in 4.10.3 a). **4.10.4 Final inspection and testing** The supplier shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.		on p. 49. → Do cytox testing as well as physical/chemical testing ↓ ask who does + how ask MR Gaussie Chem-testing all done by supplier. → checked cyto.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorised.

4.10.5 Inspection and test records

The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records shall identify the inspection authority responsible for the release of product (see 4.16).

The supplier shall record (see 4.16) the identity of personnel performing any inspection or

Sapherz8m

ON Device File. – released by M. Burel, Soph. (##) has authority to release as well.

The SOP identifies them.

→ The Device File indicates each area that signs off on each Q.C. point.

Organisation Name: Poly Implants Protheses

Conformity Assessment Audit date(s): 17-19 November 2003.

testing. ~~FME~~ Schedule for testing pressures every week, water every 2nd week (by P.I.P.) + subcontractor Manometer is checked by P.I.P. Environ and this is used as the correct data rather than subcontractors data Record from PIP - reading is 30	⊕ on manometers are done by Environment people. ← Records from subcontractor 2003 check Week ~~31~~ 26 → Trempage 1 (reading is 27)	← Manometers – Filling, Gluing, Laser Marking, Washing, Packaging markers → lower ← upper checked every week – records of weekly checks ~~one~~ near manometer ⊕ closed weeks 29 → 31 in 2002 = manometer ~~…~~ readings not present – crossed out scribbles on manometer readings — **NC** – Environment people ~~check~~ stay with subcontractor when he changes

not done yet ← week 47 '20' for Trempage 1 outside lower limit

Ask Environ. people.

Issue: ~~there~~ doesn't seem to be a method for following through out-of-limit readings at point of use } → check c̄ Environmental Gx FME 600/04 details ~~how to ch~~ what to do in case of out of range

← over page

Prepared by: [redacted]

* NB/Cofrac are the French equivalent of NATA.

4.11 Control of inspection, measuring and test equipment

4.11.1 General

The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation or servicing, and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).

Where the availability of technical data pertaining to the inspection measuring and test equipment

* Ask for procedure for dealing ℰ Subcontractors → All in Metrology. SOP.

① Penetrometer : Item #~~46~~ 48 88.
verif 15/1/2003
due 01/04

do according to in-house test with 3 standards - all in specification

② Micrometer : Item 051
verif. 7/4/2003
due 4/04 ✓

Once a year ~~tested~~ calibrated by a Subcontractor - accredited by "Apave" → who are linked to Cofrac (accredited by Cofrac)

③ MTS 47

Ask re measurement uncertainty ("Incertitude totale") → for instruments where relevant eg. penetrometer

③ MTS calibrate once a year

no for of inspection

is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate. NOTE 17 For the purposes of this International Standard the term " measuring equipment" includes measurement devices. **4.11.2 Control procedure** The supplier shall: a) determine the measurements to be made and the accuracy required and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision; b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognised standards. Where no such standards exist, the basis used for calibration shall be documented; c) define the process employed for the	Have they id. standards? Check micrometer	The {calibration records / certificates checked all had an area for standard / in house method identified → done using an EoFrac accredited testing house. The penetrometer was done using an in-house method.

calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;

d) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

e) maintain calibration records for inspection, measuring and test equipment (see 4.16);

f) assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;

g) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

h) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;

i) safeguard inspection, measuring and test facili-

- Ask how long calibration data is kept.
→ Should always ask what they do if they find something out of calibration
OK - checked micrometer

SOP says they're Level 7 and to keep for 15 y.

All instruments have a P.T.P. sticker that has an item number, a date verified & due date.

~~Kept for~~ SIS ~~Not thrown out~~
checked SOP & they're keeping currently for 15 years — Level 7
- currently have plenty of space

→ yes. penetrometer done at specified temperature.

→ are in Ley building but are moving to Bruxelles, the manufacturing building so as to be closer.

ties, including both test hardware and test software, from adjustments which would invalidate the calibration setting. *	Ask re what checks the validity of MTS software. Computing Dept. is responsible for the networking systems, develop + maintenance of software	-asked what would happen to MTS if the software failed – replied there is a calibration check in the software that checks the machine each time it is turned on ↳ acceptable. software not in production side ie only for records. the MTS software was purchased ē instrument & validated by MTS – there was no adapting by P.I.P. Testwork™ software

+ ✓ Database exists that traces any computerised action

* locked for everyone except for designated computer personnel who are trained by company that ~~has~~ makes software

1/ laser marking
2/ label printing
3/ MTS

} - only areas where real ~~they~~ have software interaction

Form XXX.Y

Prepared by: [redacted]

✓ currently ~~these are~~ laser marking hardware change. not software change

4.12 Inspection and test status		
The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorised concession (see 4.13.2)] is dispatched, used or installed	See 4.13 - Status labelling	A+B issue on MED 6 6400 in warehouse

4.13 Control of nonconforming product

4.13.1 General

The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

4.13.2 Review and disposition of nonconforming product

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be

a) reworked to meet the specified requirements,

b) accepted with or without repair by concession,

Bimonthly report to Quality Meeting on N.C.

identifies

~~FFA~~ 110/01, photos in FFA 190/05 to me - these were not clearly visible since obscured by boxes + panniers.

- check on non-conformity during prodn & return - what do they do c/ it.

look at in "Corrective Action".

→ No - 1

→ ~~the~~ client accepts on ~~part~~ to a schedule they are discarded

see 5.1.3. + ask re non-conformity prod? since they have a limit in the warehouse that deals c/ this

- SQI/13 PCD 001.
- all serial numbers that are for non-conform product are noted on Non-Conformity report SQI/13 FOR 400(8). - they non-conformity product is identified by photo (procedure FFA 110/01) in packing room - for other areas of clean room the staff have to be trained (as do packing staff) to identify non-conformities

→ each staff member reports any N.C. to their supervisor and depending on where that NC is detected the QM or QMT makes the decision on what to do "sans delai" if it is during production.

contractural basis that if the tested samples they are retested + if fail again

All easily retrievable !

c) regraded for alternative applications, or d) rejected or scrapped. Where required by the contract, the proposed use or repair of product [see 4.13.2b)] which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16). Repaired and/or reworked product shall be re-inspected in accordance with the quality plan and/or documented procedures. *The supplier shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. The identity of the person authorizing the concession shall be recorded (see 4.16).* *If product needs to be reworked, the supplier shall document the rework in a work instruction that has undergone the same authorization and approval procedure as the original work instruction.*	– non-conforming product (after testing and or just visual) is stored in a locked designated area until destruction (incinerated) → Yes TS has a SOP. don't repair or rework. yes – Q.M. must authorise.	N.C	There is a doc SQ1/20 PCD 001 which has statistical values based on which what to do with non-conformities "Statistical Management of non-conformities coming from production" Lot 21503 – titanium implant – have requested their subcontractor (Lab Chem Mech Test lab) ~~plasma coats~~ improve the allowable range for coating ie. reduce range of upper + lower limit " Asked to see a non-conformity from gel implant – the last one was 2110 ~~Caution~~ – % reject 37°C – reason was patch detachment due to bubbles the CAR requested (02/07 Sept 2002) showed that the analysis found it was the pressing instrument that was defective and this was modified. Mr Gossard ↓ see above.

4.14 Corrective and preventive action		
4.14.1 General The supplier shall establish and maintain documented procedures for implementing corrective and preventive action. Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action. **4.14.2 Corrective action** The procedures for corrective action shall include: a) the effective handling of customer complaints and reports of product nonconformities; b) investigation of the cause of non conformities relating to product, process and	2 explanted implants are given ~~sep~~ unique I.D. but kept in same file. (it is usual to explant both implants even if only one has ruptured). (Levels of rupture for the TX were on average 0.02 # ← 0.035 % depending on site (Good	Request for 'evaluation' from customers (Mag D1) ↳ maybe need to see some of these. * . CAR: procedure SQ1/14 PCD 001 → document & maintain documented procedures SQ1/14 PCD 001 contained a ✓ b ✓ c ✓ d ✓ → imp. plan + check new batches to see its worked.

quality system, and recording the results of the investigation (see 4.16);

c) determination of the corrective action needed to eliminate the cause of nonconformities;

d) application of controls to ensure that corrective action is taken and that it is effective.

The supplier shall establish and maintain a documented feedback system to provide early warning of quality problems and for input into the corrective action system.

If this standard is used for compliance with regulatory requirements which require post marketing surveillance, this surveillance shall form part of the feedback system.

All feedback information, including reported customer complaints and returned product, shall be documented, investigated, interpreted, collated and communicated in accordance with defined procedures by a designated person.

If any customer complaint is not followed by corrective action, the reason shall be recorded.

The supplier shall maintain records (see 4.16) of

→ each treated separately in in the SOP.

→ SOP for each ~~of~~ identified in (b)

→ Implementation program is

→ SOP id. above.

N.C. report issued 1st NO CAR. reason is indicated in SQ1/14 PCD 002 in flow chart p.5

→ for when they don't receive explans (all received ones followed thru).

In France, getting explanted devices back is difficult to law but surgeons do send them back if surgeon wants to
In USA – receive when they can

checked off – the QM manager signs off that it is implemented & there is a schedule
→ this is described in Non-Conforming Product

→ SOP for France, 'MDA' and other countries re dealing with complaints – described further in SQ1/14 PCD 004. + 5.2. Recall Communication.

→ Yes on forms specific to what the issue was – for explanted implants the SQ1/14 FOR 501. → Q.M. conveys vigilance report

→ Recall procedure SQ1/14 PCD-004 – 3 classes of recalls. – depends on regulatory jurisdiction (ie ~~The~~ EU, France, USA rest of world)

all complaint investigations. When the investigation determines that the activities at remote premises played a part in the complaint, a copy of the report shall be sent to those premises. *If this Standard is used for compliance with regulatory requirements, the supplier shall establish, document and maintain procedures to notify the regulatory authority of those incidents which meet the reporting criteria.* *The supplier shall establish, document and maintain procedures for the issue of advisory notices and the recall of medical devices. These procedures shall be capable of being implemented at any time.*	If ~~the contract~~ identifies defect report is communicated to Surgeon Do they have ~~reg~~ doc. procedure for reporting to reg. auth. → to sponsor in Australia → identify, (2) recall communicat	→ Documented procedure for each regulatory jurisdiction – showed me Vigilance reports re explanted implants – Yes on specific form SQ 1/14 FOR 501 → depends on country, vigilance report is sent to the relevant Health Ministry in the country → evaluation report closure.
4.14.3 Preventive action The procedures for preventive action shall include: a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyse and eliminate potential causes of non conformities;	– showed me !!! IRIS reports for a saline implant to AUSTRALIA – 02/02.	SQ 1/14 PCD 001 also documents preventative actions H.F. → Showed me forms where internal audits, management reviews, NCRS, staff from process, service reports SQ 1/14 FOR 400 – identifies if it is a – corrections – corrective action – preventative !!

b) determination of the steps needed to deal with any problems requiring preventive action; c) initiation of preventive action and application of controls to ensure that it is effective; e) ensuring that relevant information on actions taken is submitted for management review (see 4.1.3).		- initiation - records - & further steps → all feed into management review thru Q-M. meetings.

4.15 Handling, storage, packaging, preservation and delivery		
4.15.1 General The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product. *The supplier shall establish and maintain documented procedures for the control of product with a limited shelf life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded.* *If appropriate, special provisions shall be made for the handling of used product in order to prevent contamination of other product, the manufacturing environment or personnel.* **4.15.2 Handling** The supplier shall provide methods of handling product that prevent damage or deterioration. **4.15.3 Storage** The supplier shall use designated storage		- doc. procedures ; Storage is at 20±2° C - in ~~front~~ at bottom - temp. control in 2° packaging room - no air con vents, technician kept opening door (no vents on door) to cool room door (building is temp. controlled). - there's an air con in room which the packers can open if they have to.

areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorising receipt to and dispatch from such areas shall be stipulated In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals. **4.15.4 Packaging** The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements. *The supplier shall establish and maintain procedures to ensure that:* *a) the medical device is presented in a container which maintains the sterility of the medical device, except for those medical devices which only the inner surfaces of the medical device are sterile and the medical device is such that the sterility of the inner surfaces is maintained;* *b) the medical device is capable of being presented in an aseptic manner, if its use so requires;*	reviewed weekly.	- A+B stickers - on p-18. → i

c) the package, or medical device if only the inner surface is sterile, clearly reveals that it has been opened. *Additional requirements for active implantable medical devices and implantable medical devices:* *The supplier shall record the identity of persons who perform the final labelling operation (see 4.16)* **4.15.5 Preservation** The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control. **4.15.6 Delivery** The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination. *The supplier shall ensure that the name and address of the shipping package consignee is included in the quality records (see 4.16).*		

The supplier shall require that any authorized representative maintains records of distribution of medical devices and that such records are available for inspection.		non-compliant goods Returned goods ↓ decide what it is – 3 categories then if it's a standard return or if it's needs testing for further evaluation The form has who returned – surgeon or other contract distributor and a space for comments regarding ~~Condition~~ dates for when it came back and where it was placed. The "surgeons" (companies ??) they have contracts with are given certain instructions of what they need to do.

4.16 Control of quality records

The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

Auditor to check

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

NOTE 19 Records may be in the form of any type of media such as hard copy or electronic media

The supplier shall retain the quality records for a

Have procedures in QM

"Device History Record".

- Completed batch records (3)

- Make sure all documentation "indexed" somehow + procedure for checking

All easily retrievable

- Showed me 24103
  24903
  22803
- they're kept in manilla folders ✓ an index page until they're all complete in at stage of release; then, put into a white folder. M. Bunce
- all signed by Quality Manager - however Sophie also has the authority (indicated on function form) to sign off each batch.
- ~~for all~~
  checked Mech tests, → all ✓ in Specs
  checked Ster. records → all ✓ in Specs for 2 of 3
  checked viscosity → all within Specs
  3 lots didn't require adjustment

period of time at least equivalent to the lifetime of the medical device defined by the supplier, but not less than two years from the date of dispatch from the supplier.	- lifetime of device	- are in process of changing to 40 years from 15 years - See 4.5.
The supplier shall establish and maintain a record for each batch of medical devices that provides traceability to the extent required by 4.8 and identifies the quantity manufactured and quantity released for distribution. The batch record shall be verified and authorized.	check -	√ yes, by Q.M. (+ Sophie who has authority) - flow of batch record documented, sighted + checked, it follows each batch through production until release, where it is stored + controlled by the person responsible for storing the Device History Record (Soph).
Note: A batch may be a single medical device.		

4.17 Internal quality audits

The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited. The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).	* Procedure * Schedule * Observation * how does it link into CAR	-SQI/17 PCn 001 — Lead Auditor assigned requests a 2nd auditor if poss. - R+D audited QA area recently - Ms. Font audited Computer Dep. recently. -types of audits: on CARS, Prev. continual improvement, HR, manufact. + control, documentation, Management Policy (Ms Font + Mr Gosse) Environmental monitoring, Storage, Contracts, Orders, Regulatory affairs, R+D. - Auditors have to be trained + designated by Q. Manager — they have to be independent of the area they're auditing. - Audit frequency can change if the Q. Manager deems it necessary. — It is deemed necessary if the following cause deviations ie. N. Conformities increase above acceptable SOP identifies

The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3).	Checked 3 reports (1 R one identified on schedule as having 1 Non-conform).	levels, CAR resulting from N-C. + Prev-Actions deem it necessary. Assessment of all internal audits is given at the last management review of the year. (1) These were to do with deciding that staff have to sign as soon as they start not after probation. (2) Identified the need that when the job description changes the whole competency procedure has to begin again (previously didn't necessarily check competence for non technical areas). Have added a question re whether staff changed area during year.

16/10/03

(2) Environment Audit – complied with observations. Observation was that the ISO Class, although in the Quality Manual was not identified in the SOP (SQI/02 PCS 010).

(3) Manufacturing – complied with observations. Observations: ~~suggested need database for Device amount of lot, date released. etc~~ – suggested that a computer in the clean room (not there currently) should be considered for clean room so that it is easier to fill in data but identified that it needs to be consistent with clean room requirements

4.18 Training		
The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience as required. Appropriate records of training shall be maintained (see 4.16). *The supplier shall ensure that all personnel who are required to work under special environmental conditions or who perform special processes (see 4.9) or functions are appropriately trained or supervised by a trained person.*	sighted records for ① Agnès LUPO - [redacted]: ADAMEL. ② QM included reports of description job / test results (approved). ③ HF Commerce / MBA Qual Medical testing for operators is twice a year (all other staff once a year). All staff who go into clean area are also tested twice a year (eg. the mechanical / environment staff). Blood tests for staff who are exposed to ~~proc~~ manufacturing process are for solvents as well as lung function.	HR. – for MTS training – Attestation certificate & signature and dated – Mentor staff for new staff ① identify need (edn / skills / experience) ② work out what needs doing / training ② 'mentor' ④ train ⑤ Assess competency → keep track re time taken. re Chemical exposure to staff, on induction they all get a booklet when they sign they have received, the booklet explains the symbols for hazardous + toxic chemicals (eg. reqm. in France) symbols for France + slightly diff. so they do these for incoming product.

4.19 Servicing		
Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.	validation of software Computing.	SQ1/02 SYN 110 – "Controlling computerised systems" → procedures for all P.I.P. comp. systems, re purchasing Tech-data in DOT SI 001 : Tech File on comp. systems ↳ See Attachment (1). ↓ this is in response to FDA questions.

4.20 Statistical techniques		
4.20.1 Identification of need The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics . *The supplier shall establish and maintain procedures to ensure that sampling methods are regularly reviewed in the light of the occurrence of nonconforming product, quality audit reports, feedback information (see 4.14) and other appropriate considerations.* **4.20.2 Procedures** The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.		SQI /20 PCD 001 For manufacturing control, have key indicators in their process control to determine the verification of statistical techniques. → Discussed in relation to complaint handling. - indicators set into system so that bi-monthly reports pick NCS exp →