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MATRAVILLE NSW 2036

PROC-009

PROCEDURE
ASSESSING VENDORS AND SUBCONTRACTORS

Prepared by:	**Date:**	**Position:** QA Manager
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The following ATTACHMENTS form part of this document.

FORM-016 Approved Vendor/Subcontractor Record

This revision supersedes all previous revisions.
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1. INTRODUCTION

1.1 Purpose of Document

To define and control the process of assessing vendors & subcontractors

1.2 Purpose of Procedure

To evaluate and select vendors & subcontractors based on their ability to supply product/services in accordance with our requirements

1.3 Scope

All vendors/subcontractors of both Portland Orthopaedics and Vimek companies for all materials and services that could have a bearing on product or service quality

This procedure replaces Vimek procedure P0601 Assessing Vendors & Subcontractors.

1.4 References

External Reference:

EN 46002 Application of EN ISO 9002 to manuf'acture of MD's

ISO 9002 Quality systems- Model for quality assurance etc

Internal References:

REG-011 Register – Approved Vendors & Subcontractors (Portland & Vimek registers combined)

FORM-016 Approved Vendor/Subcontractor Record

1.5 Responsibility/Authority

The responsibility and authority for the procedure is with the Management Representative, who has the authority to delegate responsibility to other people to carry out the work.

1.6 Definitions

Subcontractor: A supplier or potential supplier to the company of materials or services to our specification.

Vendor: A supplier or potential supplier to the company of materials or services to their specification i.e. a standard commercially available item.

2. PROCEDURE Assessing Vendors & Subcontractors

2.1 Evaluation Levels

When a new subcontractor/vendor is required, the company will be subject to an approval screening process. The amount of evaluation depends on how much the vendor/subcontractor affects the company's product.

There are three categories of evaluation:

- Low – Little or no effect on product quality: (product or services not related to the product but general running of the company e.g. Stationery).
- Medium – Limited effect on product quality and the quality can be inspected: (e.g. subcontractors for verification or instrument supply, subcontractors for operations that can be inspected like laser etch).
- High – Major effect on product quality or the quality cannot be inspected: (e.g. implant special processes including cleaning, packaging, sterilization or implant final products).

These categories are evaluated using the criteria below:

Low: Vendors/Subcontractors meet requirements generally.

Medium: Vendors are approved on the basis of the following criteria:

- They being a sole supplier of the required goods/services
- Sample product evaluation has been conducted
- Referral by existing customer / approved supplier
- Based on published review of company / product.

Medium: Subcontractors are approved on the basis of the above vendor criteria and:

- AS/NZS ISO 9002 or equivalent certification status
- Previous known history of acceptable service / goods
- In the absence of any of the above, an Audit or surveillance visit will be made by a Management Representative or his Delegate (see below)

High: Extra control is required. This can be supplied by a combination of:

- Third party certification to EN46002, or equivalent (e.g.) FDA approval
- Contract or GMP Agreements
- Any other method supplying control e.g. extra testing or other direct control

2.2 Evaluation

Responsibility: Requesting Manager

Task

General enquiries. Gather information (brochures etc). This can be facilitated by asking potential suppliers to complete a form similar to that in Appendix B or C.

Assessment. Assess against specified criteria. This can include site visit or inspection of samples where appropriate. If an Audit or surveillance visit is required, the Management Representative or his Delegate can follow a checklist of issues listed in Appendix B or C and perform any other assessments considered relevant. A record of the visit will be made, signed and dated.

Specification. Check the purchasing specification is adequate, especially any testing or QA requirements to be applied to the contract. Responsibility clarification can be done with GMP Agreements.

Authenticate the findings by signature and date.

Documents or Records to be Produced

Vendor / sub-contractor records for medium & high levels of evaluation include the following details as appropriate on Approved Vendor/Subcontractor Record FORM-016.

- Indicate if Vendor or Subcontractor
- Company name
- Address (street and postal)
- Telephone and facsimile numbers
- E-mail address (if available)
- QA contact (if known)
- Credit terms and any special arrangements
- Products and services supplied
- Approval Criteria
- Approval Signature & Date

Low level evaluation records also should be kept where a large amount of business occurs but not required for small purchases.

Any records to be kept (e.g. certification certificates) can be attached to the record.

For important subcontractors or if there is a large amount of records, then make a file to hold any history on subcontractor to help in future reviews. These files are to be held by Manager using Vendor/Subcontractor.

2.3 Approving

Responsibility: Requesting Manager

Task

All Subcontractor and Vendor are to be approved by Portland Management Representative. The Manager Production is authorised to sign off approvals after verbal approval.

Portland Management Representative will have vendor entered in Exchequer database.

Documents or Records to be Produced

Approval signature on completed Form-016

Exchequer entry.

2.4 Filing

Responsibility: Requesting Manager

Task

Approved Vendor/Subcontractor records (FORM-016) are filed in REG-011. Update the listing (Exchequer listing has limited access) for convenience of Technology. This is to contain:

- Company Name
- Product/Service
- Type: Vendor (V), subcontractor (S) plus with separate history file (F)
- Status - Current (C),
  Not Current i.e. not to be used (NC),
  Not Preferred but approved (NP)
- Any other information that is handy

This can include a listing for easier referencing.

Documents or Records to be Produced

Possible entry on listing in REG-011.

3. PROCEDURE Monitoring Vendors & Subcontractors

3.1 Reviewing (Monitoring)

Responsibility: Manager using Vendor/Subcontractor

Task

A review occurs to determine if vendor/subcontractor is acceptable when:

a) A problem could be happening with a vendor/subcontractor;
b) Vendor/subcontractor has not been used for a period of time;
c) A review has not occurred for a year.

If a Vendor / Subcontractor is Not Current, then no review is required unless they are to be used again.

The review is based on available information, mainly past performance. For example:

- monitoring the results of periodic inspection of products or services received;
- Certification of Quality system by third parties;
- Test certificate of analysis result;
- Auditing quality system for subcontractors (Visiting, see 3.2).

Documents or Records to be Produced

The review should be noted by signing off with results on FORM-016

3.2 Visiting (Monitoring)

Responsibility: Manager using Vendor/Subcontractor

Task

Where a subcontractor carries out special process (i.e. a process that cannot be inspected) then this subcontractor should be visited at least once a year and if possible, two years for overseas subcontractors.

The visit is to determine if the subcontractor is in control of the process. The following could be discussed:

- Any past non-conformances;
- Any potential problems;
- Quality system status (this can include an audit)
- Reviewing the process in action.

A record of the visit (report etc) made & signed. A copy place in vendor file and registered in Subcontractor Visit Schedule & Register.

The Subcontractor Visit Schedule & Register contains following fields:

- Subcontractor;
- Process;
- Schedule;
- Visit Date;
- Report Location; &
- Report by.

Documents or Records to be Produced

Visit Report

Entry in Subcontractor Visit Schedule & Register

3.3 Method of Removal of Vendor/Subcontractor

Responsibility: Manager using Vendor/Subcontractor

Task

If vendor/subcontractor is found to be not acceptable, then the problem is to be discussed with vendor/subcontractor.

If it cannot be resolved, then a new vendor/subcontractor is to be found. These reasons can be:

- an unacceptable pattern of non-conformance of supplied product or service;
- an unacceptable change in quality assurance status;
- any other reason deemed unacceptable by the responsible person.

The old vendor/subcontractor is to be marked as not preferred or not to be used. The records in REG-011 are to be retained for life of the product.

Documents or Records to be Produced

Possible entry in listing in REG-016. If a vendor/subcontractor is no longer being used, then mark their status as "Not Current" (NC). Upon review, they can be used again if previous records are still correct and status changed to "Current". If vendor/subcontractor goes out of business or being dropped, then remove them from the list.

Retain the "Not Current" and superseded records & registers in a separate file with the approved vendors / subcontractors file for convenience.

4 PROCEDURE Assessing the vendors and sub-contractors of Portland's Coordinating sub-contractors

4.1 Subcontractors of Vimek Pty Limited

Responsibility: Manager using Vendor/Subcontractor

Task
As long as Vimek Pty Limited remains a principal subcontractor of Portland Orthopaedics Pty Limited, the Management Representative will rely upon the approval of Vimek of a vendor or subcontractor. Where it is stated in Portland's Specifications that only an Approved Vendor/Subcontractor shall be used, those that are used will be reviewed by Portland, and a record of such review will be made on FORM-016 by the signature of the CEO or CTO.

Documents or Records to be Produced
Possible signature of the CEO or CTO on FORM-016

APPENDIX A

RECORD OF CHANGES

Issue No.	RECORDED AMENDMENT	DATE	DCN #
1	Release	13.09.2001	21
2	Added 'Responsibility' & 'Documents or Records to be Produced' paragraphs to sub-sections in sect 2. Sect 2.1 More explanation added Sect 2.2 Renamed & rewritten to make process clearer. Sect 2.2 Added Exchequer entry. Sect 2.3 Added entry onto Register Listing Section 3 Reviewing made a separate section as it not part of previous process but occurs later Added more details Section 4 was old section 3 Added Appendix C	3/6/03	0077
3	Change to a Portland Group Procedure by adding details from Vimek P0601 and adding section 2.3 Method of Removal of Vendor / Subcontractor		

APPENDIX B Subcontractor Surveillance Checklist

COMPANY NAME
1. Who has immediate authority for Vimek orders?
2. Who is responsible for performing the specified operation(s)?
3. What are the operator training requirements?
4. Has the operator been trained and is it recorded?
5. What equipment is required?
6. What equipment is available and how is it maintained?
7. Is the operation a special process? Y / N a) How are the process parameters controlled b) How are the process parameters monitored
8. What are the documentation / record requirements (any pre-settings etc)?
9. Where are documents / records stored and are they accessible to operators?
10. What in-process inspections are performed?
11. What final inspection is performed?
12. How is work scheduled?
13. Is additional information required to ensure subcontract process conforms to specification(s)?

APPENDIX C Subcontractor Evaluation Questionnaire

COMPANY NAME **Address** Phone/Fax
Name/Title of Person Completing This Survey Date
Does your company have a formal quality program and QA/QC department?
Does your company have a Quality Manual available for us to review?
If you answered no to question above, is there an index of Standard Operating Procedures you would be willing to send us?
Is there a formal employee training program for all employees that do work that could affect quality of our products?
Are personnel formally trained through either a training program or prior education and experience or a combination of both?
Is training planned and documented in an ongoing record?
Do you conduct a formal review of customer orders to ensure that customer requirements can be filled?
Do you have a formal incoming inspection procedure for materials used in the manufacturing process?
Do you use accept/reject criteria to decide whether to accept incoming materials?
Do your raw materials suppliers provide Certificates of Conformance or Analysis with each lot shipped?
Do you perform verification testing on any materials?
Do you have written procedures for the control, storage and issuance of materials used in production?
Do these procedures include identification and segregation of materials prior to use?
Are these procedures in place that provide advance notice to your customers of process changes that could affect the quality of the customer product?
Do you have a First In, First Out policy?
Please describe your level of component traceability?
Do you have written in-process inspection procedures?
Do you have cleaning and/or preventive maintenance procedures for your production equipment?
Do you have a calibration program for production and test equipment?
Do you have a calibration program for your production and test equipment?
Is QA responsible for approving final product for release and shipment? If not, please indicate who is? Name/Title:.....

Do you have a formal document control system for changing and controlling product specifications?
Do you have procedures that describe how to handle and document non-conforming products?
Do you have a formal Customer/Product complaint system?
Do you have a Customer Service program?
Do you have a formal returned goods policy?
Do you have a formal documented supplier qualification program?
Do you perform supplier quality audits or other types of surveillance or qualification activities? Please describe any surveillance activities?
How long are production records kept?
Do records archived include inspection documents, raw material certificates and receiving and shipping records?
Please add any other information or comments you would like us to know in our evaluation of your capabilities.