

UNICORN 5.0 audit checklist



| | |
|---------------|----------------|
| Edition AA | 257426975-S365 |
| page | Page 1 of 15 |
| Date | 2004-01-22 |

| |
|-----------------|
| Author(s) |
| Stina Häggström |

| | |
|--|-----------|
| ABBREVIATIONS, ACRONYMS AND REFERENCES | 2 |
| A. COMPANY OVERVIEW | 3 |
| B. ORGANIZATION AND QUALITY MANAGEMENT..... | 4 |
| C. PLANNING AND PRODUCT/PROJECT MANAGEMENT | 6 |
| D. SPECIFICATIONS | 7 |
| E. IMPLEMENTATION..... | 8 |
| F. TESTING..... | 9 |
| G. COMPLETION AND RELEASE..... | 11 |
| H. SUPPORT / MAINTENANCE | 12 |
| I. SUPPORTING PROCESSES AND ACTIVITIES..... | 13 |
| APPENDIX PROTEIN SEPARATIONS SENIOR MANAGEMENT (JANUARY 2004) | 15 |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 2 (15) |

Abbreviations, acronyms and references

| | |
|--------|---|
| AfU | Approval for Use |
| BMI | Business Management Information. Part of Amersham Biosciences' QMS system holding policies, procedures, instructions, templates etc |
| dbPlus | Error tracking system for error reports filed during product development. |
| CASE | Computer Aided Software Engineering |
| CSSx | Customer Satisfaction System, System for tracking customer feedback. |
| ISPE | ISPE is a global, not-for-profit membership organization that provides education, training, and technical publications to Life Science professionals. |
| MDD | sw Module Design Description |
| FOC | Free Of Charge |
| N/A | Not Applicable |
| OPP | Outline Project Plan |
| OPC | The OPC Foundation is dedicated to ensuring interoperability in automation by creating and maintaining open specifications |
| PARC | Lotus Notes based Project Archive for documentation. |
| PCCR | Project Contract Change Request. |
| PMG | Project Management Group, representing Business Area heads |
| QA | Quality Assurance |
| QMS | Quality Management System |
| R&D | Research and Development |
| Sw | Software |
| SDD | Sw Design Description |
| SDP | Sw Development Plan |
| STD | Sw System Test Description |
| SVD | Sw Version Description |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 3 (15) |

A. Company Overview

| | Item | Comments |
|-----|---|--|
| A.1 | Audit details (address, audit team, supplier representatives) | Amersham Biosciences AB Organisation number: 556108-1919 Visiting Address: Björkgatan 30, Uppsala Postal address: SE-751 84 Uppsala |
| A.2 | Company size, structure and summary of history (number of sites, staff, organizational charts, company history) | Amersham Biosciences Protein Separations: Headquarters in Uppsala, Sweden. R&D and manufacturing sites in Sweden and USA. Global sales and service organisation. The products are used in the manufacture of over 90 per cent of all biopharmaceuticals on the market. 1,950 employees worldwide. See Appendix A for organisation charts |
| A.3 | Product/service history (main markets, how many sold, use in healthcare sector) | Products: Chromatography purification systems, membrane products and media used in the manufacture of biopharmaceuticals (any biologically-derived drug, e. g. insulin, vaccines, DNA-based medicines, anti-sense DNA, growth factors, monoclonal antibodies, interferon), and for the laboratory scale separation of proteins for research and drug development. Main Markets: Biopharmaceuticals are drugs based on active molecules such as proteins, peptides or DNA. Manufacture of these biological drugs requires the purification of the molecules on an industrial scale, which is done using large advanced chromatography systems comprising columns packed with separations media. We are a clear market leader in this area, with over 40 years of experience. Over 10000 UNICORN™/ÅKTA™ installations world wide Over 2000 UNICORN/BioProcess™ installations. |
| A.4 | Summary of product/service under audit (product literature) | UNICORN 5.00 |
| A.5 | Product/service development plans | UNICORN is a key part of Amersham Biosciences systems offering. Amersham Biosciences is committed continue the development and support of UNICORN. |
| A.6 | Tour of facility (to verify housekeeping, general working environment, working conditions) | N/A |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 4 (15) |

B. Organization and Quality Management

| | Item | Comments |
|-----|---|---|
| B.1 | Management structure (roles, responsibilities) | <p>The quality management system can be defined as all activities needed to ensure that our customers receive quality, reliability and integrity in the products and services provided, and that customer needs and requirements are met. The system calls for strict adherence to specifications as well as regulatory and quality requirements, and conforms to the specified requirements of ISO 9001:2000.</p> <p>The Protein Separations quality management system is based on a process and system approach, and it encompasses the steering structures and procedures needed to achieve the company's business objectives. The quality management system includes all company functions and applies to all company sites.</p> <p>Each operation unit has a QA department reporting to the head of unit, having also a dotted line to the Vice President for QA reporting to the President for the business area Protein Separations. See also Appendix A</p> |
| B.2 | Method of assuring quality in product/service (quality system, responsibilities for quality) | See Protein Separations Quality Manual (BMI 70-5035-30) and Protein Separations Quality Policy (BMI 70-5035-31) |
| B.3 | Use of a documented Quality Management System (QMS) e.g., existence of a quality policy and objectives, quality manual, process definitions/procedures, standards | See Protein Separations Quality Manual (BMI 70-5035-30) and Protein Separations Quality Policy (BMI 70-5035-31) |
| B.4 | Maturity of QMS (relevance to product/service under audit) | A QMS for Software development has been in place since the start of UNICORN development 1991. |
| B.5 | Control of QMS documentation (reviews, approvals, distribution, updates) | Archived (approved) documents are accessible electronically by all employees. The review and approval process is described in documents, BMI ref no 70-5010-06 Updating BMI with new or changed documents and 70-5017-44 Electronic workflow in BMI. Outdating documents is described in document BMI ref no 70-5020-82. |
| B.6 | Maintenance of QMS documentation (regularly reviewed and updated when appropriate) | Internal audits are performed at the local level on a periodic basis (BMI ref no 70-5009-07 Internal audit of the management system). |
| B.7 | QMS certified to a recognized standard (e.g., ISO9001) | Amersham Biosciences is ISO 9001 certified. ISO 9001:2000 has been implemented and audited during 2003. Original ISO 9001 approval was issued 1993. |
| B.8 | Method of checking compliance with QMS (internal audits, management reviews) | Internal audits are planned in advance. Internal auditors are selected, trained and deployed at each site. Managers are accountable for addressing non-conformances that are identified during the internal audit (see Corrective action from internal audits, 70-5009-08). Records are stored at the local level with results being reviewed during management review (see Management review Protein Separations, 70-5031-31). |
| B.9 | Qualification and suitability of staff | Development needs are assessed on a yearly basis and included in the individual's development plan. See BMI ref no 70-5032-91 Template for Utvecklingsamtal, Performance and development discussions 70-5011-21. Qualification requirement for project roles are defined in the Sw Development Plan (SDP) |

UNICORN 5.0 audit checklist



| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 5 (15) |

| | | |
|------|--|---|
| B.10 | Independence of auditors, inspectors, testers, reviewers | <p>Auditors for ISO 9000 are from LRQA (Lloyds' Register Quality Assurance). The internal audit of the quality system see B.8.</p> <p>A software project is reviewed in different levels: Internal Sw Project QA – A project role defined in the SDP administrates internal project reviews. Internal R&D QA Review – Sw QA function outside the Sw Department</p> <p>For UNICORN in particular an External audit is performed by an independent external auditor</p> |
| B.11 | Staff training (general, QMS, product/service related, new staff, changes to QMS, regulatory issues, training records) | <p>Changes in the QMS are recorded and notified in e-mails. Re-training is made for larger updates.</p> <p>Development needs are assessed on a yearly basis and included in the individual's development plan. See B9. As a result each individual that is developing the UNICORN sw, including contractors, has to have a plan for GMP training and re-training. Training records are included in each individual's CV. The CV is updated at least once a year as part of the follow up of the development plan. Course certificates are kept in the individual's personal binder. A record on BMI training is kept.</p> |
| B.12 | Use of sub-contractors (individuals, companies): - Method of selection - Sub-contractor qualifications and training records - Specification of technical and quality requirements in orders placed - Method of accepting product delivered by sub-contractor | <p>Competence and training of each individual is assessed in dialogue with the Contractor organisation. CVs are available, including training, for each contractor. UNICORN contractors work in accordance to Amersham-Biosciences' QMS. An ISO 9000 certified contractor, Prevas, has been used for UNICORN 5.00 development. See also BMI ref no 70-5012-42 Consultant selection.</p> |
| B.13 | Experience of validation process (with other customers, previous Supplier Audits, services provided by supplier, involvement in regulatory inspections) | <p>Amersham Biosciences now has over 10 years of experience in development of regulatory compliant software. Amersham Biosciences' Fast Trak organisation provides services in Regulatory Support, including training, IQ/OQ documentation, Change Control and development of SOPs.</p> |
| B.14 | Awareness of healthcare regulatory requirements (knowledge of regulations, subscription to publications, attendance of relevant events, involvement in industry groups) | <p>The Fast Trak organisation is constantly monitoring the development in the regulatory area. Validations trainings are part of Fast Trak's training package offered to customers.</p> <p>Separations Software, together with Fast Trak, have chaired two validation conferences, arranged by IBC Euroforum the last 12 months. Each developer has been trained in GMP and Part 11 implications for computerised systems. See B.11 above.</p> <p>Separations Software have members in ISPE Amersham Biosciences are members of OPC foundation</p> |
| B.15 | Continuous improvement programme (use of metrics to evaluate and improve effectiveness of QMS) | <p>The key business management processes are identified in the Quality Manual, 70-5035-30 The monitoring and measurement of these key business processes is accomplished primarily through the internal audit program (see Internal audit of the management system, 70-5009-07); through Management review (see Management review, 70-5031-31); and through department review of internal processes and procedures. Improvements can be brought to the attention of the appropriate manager through a corrective action (see Corrective action from internal audits, 70-5009-08) or through department meetings. Metrics are established by various departments to provide feedback as to business performance and adequacy of processes.</p> |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 6 (15) |

C. Planning and Product/Project Management

| | Item | Yes/No | Comments |
|-----|--|--------|--|
| C.1 | Use of quality and project plans (per project/product, defining activities, process definitions/procedures, responsibilities, time scales) | Yes | The Project is outlined in the Outline Project Plan (OPP) BMI ref no 70-5010-14 Software Development is refined in the Sw Development Plan (SDP) BMI ref no 70-5012-20 UNICORN 5.00 OPP; PARC Doc ref no 227616980-L632 UNICORN 5.00 SDP; PARC Doc ref no 224675755-L632 |
| C.2 | Status of planning documentation (reviews, approvals, distribution, maintenance, and update) | Yes | Planning documentation is maintained and updated, reviewed, approved and distributed on-line using the project archive (PARC) Review documentation is filed in PARC. Example: UNICORN 5.00 OPP approval; PARC Doc ref no 225775190-L314 |
| C.3 | Documentation of user/supplier responsibilities | N/A | UNICORN is an off-shelf product. |
| C.4 | Use of Validation Plan where supplied by user company | N/A | UNICORN is an off-shelf product. |
| C.5 | Project management and monitoring (mechanism, tools, progress reports) | Yes | Progress reports are filed as Status Reports, project BMI ref no 70-5031-42. Status Reports are reviewed in PMG. Example: PARC Doc Ref no for UNICORN 5.00 Status Report: 253623887-L632 |
| C.6 | Accuracy of, and conformance to, planning and management process definitions/procedures | Yes | Assessed in Software QA Report, project BMI ref no 70-5020-45 Followed up in Phase Exit reviews, Development (D) project BMI ref no 70-5010-05 and at Approval for Use, see Sw development handbook BMI ref no 70-5012-08. Example: UNICORN 5.00 Software QA Report; PARC Doc ref no 250060571-C516 AfU of Zappa Unicorn 5.0 build 315; PARC Doc ref no 257948235-C516 |
| C.7 | Use of formal development life cycle | Yes | Development process overview BMI ref no 70-5011-94 Development (D) project BMI ref no 70-5010-05 Sw Development procedure BMI ref no 70-5012-32 Sw development handbook BMI ref no 70-5012-08 |
| C.8 | Evidence of formal contract reviews where applicable | Yes | Followed up in Phase Exit reviews, Development (D) project BMI ref no 70-5010-05 PD Phase review checklist BMI ref no 70-5012-73. Example: UNICORN 5.00 Phase 2 Exit Review Report; PARC Doc ref no 224659191-C516 |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 7 (15) |

D. Specifications

| | Item | Yes/No | Comments |
|-----|---|--------|--|
| D.1 | User Requirements Specifications | Yes | Technical Specification (TS) BMI ref no 70-7611-09 PARC Doc Ref no for UNICORN 5.00 TS: 208929482-M245 |
| D.2 | Functional Specifications | Yes | Software Requirement Specification (SRS) BMI ref no 70-5012-21 PARC Doc Ref no for UNICORN 5.00 SRS: 224852556-L632 |
| D.3 | Software Design Specifications | Yes | Software Design Description (SDD) BMI ref no 70-5012-26 PARC Doc Ref no for UNICORN 5.00 SDD: 225777444-M423 |
| D.4 | Hardware Design Specifications | N/A | UNICORN is a software product |
| D.5 | Relationship between specifications (together forming a complete specification of the system which can be tested objectively) | Yes | The TS is detailed and refined in the SRS. Given the SRS the Overall Design is documented in the SDD. The design of the individual modules are documented in Module design Descriptions (MDDs) |
| D.6 | Traceability through specifications (e.g., for a given requirement) | Yes | A requirements is defined in the SRS. It is then referenced and verified in the STD. |
| D.7 | Status of specifications (reviews, approvals, distribution, maintenance and update) | Yes | Specifications are handled in Lotus Notes based Project Archive PARC, where the status of each document can be viewed and managed on-line |
| D.8 | Accuracy of and conformance to relevant process definitions/procedures | Yes | Checked in reviews. Assessed in Software QA Report BMI ref no 70-5020-45 Followed up in Phase Exit reviews, see C6 and C8. PARC Doc Ref no for UNICORN 5.00 Software QA Report: 250060571-C516 |
| D.9 | Use and control of design methodologies (CASE tools) | Yes | Guidelines available on the intranet. |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 8 (15) |

E. Implementation

| | Item | Yes/No | Comments |
|-----|--|--------|--|
| E.1 | Specification of standards covering the use of programming languages (e.g., naming and coding conventions, commenting rules) | Yes | Guidelines are available on the Intranet. |
| E.2 | Standards for software identification and traceability (e.g., for each software item; unique name/reference, version, project/product reference, module description, list of build files, change history, traceability to design document) | Yes | Software Version Description (SVD) BMI ref no 70-5012-31 UNICORN 5.00 SVD; PARC Doc ref no 242203755-K425 |
| E.3 | Standards for file and directory naming | Yes | Guidelines are available on the Intranet. |
| E.4 | Use of build files to compile and link individual software configuration items into a formal release of the software product | Yes | See E.2 above. |
| E.5 | Use and version logging of development tools (e.g., compilers, linkers, debuggers) used for each software configuration item and the formal build and release of the software product | Yes | Microsoft™ SourceSafe™ is used for Configuration Management (CM) during development. The identification and version of files and documents in the release is described in the SVD. |
| E.6 | Evidence of source code reviews prior to formal testing (checking design, adherence to coding standards, logic, redundant code, identification of critical algorithms) | Yes | Source code reviews is part of the development. Documented in Sw Review Report (SRR) BMI ref no 70-5012-19 Guidelines for review are available on the intranet. Example: PARC Doc Ref no for UNICORN 5.00 Resent Files List Module SRR: 251173702-T223 |
| E.7 | Independence and qualifications of reviewers | Yes | Review of documentation and source code is part of the project activities administrated by the project member assigned the project QA role. The role requires general competence in software development, GMP competence and BMI training. Peer Technology reviews are performed by the line organisation. Internal reviews of the project are conducted by a QA responsible person outside the Software Department. The internal auditor is TickIT certified. External audit of the project is performed by an independent auditor. The External Auditor, Dr Sandy Weinberg, is a leading expert in the field with more than 20 years experience in providing the biomedical industries with advice, auditing and regulatory services. |
| E.8 | Source code reviews recorded, indexed, followed-up and closed off (with supporting evidence). Evidence of timely management action for reviews which remain open. | Yes | See also E.6. |
| E.9 | Listings and other documents used during source code reviews identified, controlled, and retained with review reports | Yes | Documented in Sw Review Report BMI ref no 70-5012-19 Example: PARC Doc Ref no for UNICORN 5.00 Resent Files List Module SRR 251173702-T223 |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 9 (15) |

F. Testing

| | Item | Yes/No | Comments |
|-----|--|--------|--|
| F.1 | Explanation of the test strategy employed at each level of development (e.g., module testing, integration testing, system acceptance testing or alpha/beta testing) | Yes | <p>Test planning and test scope is described in the Sw Development Plan BMI Ref no 70-5012-20</p> <p>Software testing is divided into: Module testing - Module Test Description (MTD) BMI ref no 70-5027-96 (GAMP equivalent: "Code Testing") Integration testing - Integration Test Description (ITD) BMI ref no 70-5027-96 (GAMP equivalent: "Software Module Testing") System test – Sw System Test Description (STD) BMI ref no 70-5012-30 (GAMP equivalent: "Software Module Testing")</p> <p>For Engineering projects Integration Tests and System Acceptance Testing is part of the production process.</p> <p>For standard systems, such as the ÄKTA design line, the system is verified by internal users using a Software Verification Plan, BMI Ref. no 70-5000-13.</p> <p>Beta testing has not been performed; all tests are done using internal equipment and personnel.</p> <p>Example: UNICORN 5.00 SDP; PARC Doc Ref no 224675755-L632 UNICORN 5.00 Method Editor MTD; PARC Doc Ref no 226986219-M423 UNICORN 5.00 ITD; PARC Doc Ref no 225787929-M423 UNICORN 5.00 Method Editor STD; PARC Doc Ref no 224769283-F250</p> |
| F.2 | Software test Specifications | Yes | See F.1 |
| F.3 | Hardware Test Specifications | N/A | UNICORN is a Software product. |
| F.4 | Integration Test Specifications | Yes | See F.1 above |
| F.5 | System Acceptance Test Specifications | N/A | UNICORN is an off-shelf product. |
| F.6 | Structure and content of each test script (unique reference, unambiguous description of test, acceptance criteria/expected results, cross-reference to controlling specifications) | Yes | Recorded in Sw Test Description (STD) |
| F.7 | Relationship between test specifications and controlling specifications (demonstrating that the system has been thoroughly tested with traceability between specifications and tests) | Yes | Recorded in Sw Test Description (STD) |
| F.8 | Evidence that test specifications cover: - Both structural and functional testing - All requirements - Each function of the system - Stress testing (repeat testing under different conditions) - Performance testing (e.g., adequacy of system performance) - Abnormal conditions | Yes | Structural testing is performed in the MTD Functional tests are preformed in the STD Requirement coverage is assessed in the STD Performance tests and Stress/abnormal test cases are covered in the MTDs Tests at application level in SVP |
| F.9 | Status of test specifications (reviews, approvals, distribution, maintenance, and update) | Yes | Test specifications are handled in Lotus Notes based Project Archive PARC, where the |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 10 (15) |

| | | | |
|------|---|-----|--|
| | | | status of each document can be viewed on-line. |
| F.10 | Formal testing procedure to execute test specifications (method of recording test results, use of pass/fail, retaining raw data, reviewing test results, progressing and resolving test failures) | Yes | <p>Test results are recorded manually for manual tests and electronically for automated tests. Test reports are stored electronically and in paper form (STDs) Test results are reviewed in the Approval for Use meeting. BMI Ref. no 70-5028-30</p> <p>Reported failures are recorded in an error report system (dbPlus) where the status can be tracked.</p> |
| F.11 | Status of test results and associated review records (indexed, organised, maintained, followed up on failure) | Yes | <p>Test results are reported in test report documents and filed in PARC. Findings are reported in the test report and logged in dbPlus. Test Findings are followed up in the AfU-meeting.</p> |
| F.12 | Involvement of QA function (as witnesses and/or reviewers) | Yes | <p>QA operates in three levels:</p> <ul style="list-style-type: none"> - The project has an assigned reviewer to assure that documentation is correct and filed properly. The review comments for each document are filed in PARC. - Independent internal QA performing Sw QA reviews during development and AfU for final product. See C6 and C8. - - Independent external review making a pre-audit during the project and an audit when the product is available. |
| F.13 | Independence and qualifications of testers and reviewers | Yes | <p>Testers fall into three categories:</p> <ul style="list-style-type: none"> - Programmers for code level structural testing, testers for functional tests, biochemists for tests at user level. - Internal reviews of the project are conducted by a QA responsible person outside the Software Department. The internal Sw auditor is TickIT certified. - External audit of the project is performed by an independent auditor. The Independent external auditor, Dr Sandy Weinberg, is a leading expert in the field with more than 20 years experience in providing the biomedical industries with advice, auditing and regulatory services. The audit report is available on the UNICORN master CD. |
| F.14 | Accuracy of, and conformance to, relevant test process definitions/procedures | N/A | Can be assessed by the user organisation in an audit. |
| F.15 | Control of test software, test data, simulators | Yes | Test data is recorded in PARC. Test software are managed in SourceSafe and archived in the Source Code Archive. |
| F.16 | Use of testing tools (documented, controlled and versions recorded in the test results) | Yes | <p>Automatic test using Rational Visual Test 6.5 are performed on module level and documented in the Module Test Reports. Example: MTD + MTR for Module After Sales Report Generator; PARC Doc Ref no 225965055-T223</p> <p>Test scripts are managed in Microsoft™ SourceSafe™ and archived in the Source Code Archive. Test tools are stored in the fireproof archive. The version of the software is recorded in the result files generated by the automatic test.</p> |
| F.17 | Traceability of test results back to the appropriate specifications/test scripts | Yes | Results are reported together with the test specification. |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 11 (15) |

G. Completion and Release

| | Item | Yes/No | Comments |
|-----|--|--------|--|
| G.1 | Documented responsibility for release of product, such as certificate of conformity, authorization to ship (including evidence that testing has been accepted with/without reservations) | Yes | Decision of product release is taken and recorded in the Project Management Group (PMG). The decision is preceded by an Approval for Use (AfU) meeting and phase exit review in R&D. For Phase 4 exit review see D-procedure BMI Ref. no 70-5010-05. For AfU see Sw development handbook BMI Ref. no 70-5012-08. UNICORN 5.00 PMG 2003-12-17 approval: PARC Doc No. 261985110-L314 |
| G.2 | Hand over of project material in accordance with quality plan/contract (e.g., release notes. Hardware, copies of documentation/software) | Yes | Project deliverables are defined in the Outline Project Plan (OPP). Products are registered in the PDM system and formally released in the system after approval from the PMG. Status of documentation etc is covered in the AfU meeting. Remaining issues from the AfU are followed up on a regular basis and in phase exit reviews. |
| G.3 | Provision of user documentation (user manuals, administration/technical manuals, update notice with each release) | Yes | Each version of UNICORN has a User Manual, extensive on-line help and a Technical and Administration Manual. Each version also has a Software Change Description document summarising changes and corrections made. |
| G.4 | Records of releases (i.e., which customers have which version of system/software) | Yes | Labcrew™ and local sales offices keep information on systems. Engineering keeps track of configurations for customised Engineering systems. |
| G.5 | Warranties and guarantees | Yes | See warranty statement distributed with software. |
| G.6 | Archiving of release (software, build files, supporting tools, documentation) | Yes | Documentation is archived in PARC. See also E2. Source code is stored in the Source Code Archive. Tools and non-electronic documentation are stored in fireproof archives. |
| G.7 | Availability of source code and documentation for regulatory inspection (e.g., use of ESCROW accounts, and which product releases are covered) | Yes | Escrow agreements may be set-up on request for individual customers. Source code and documentation are available for on-site inspection. |
| G.8 | Customer training (summary of courses provided by staff or third parties) | Yes | A number of different training courses are offered by Fast Trak. See web for details. |
| G.9 | Accuracy of, and conformance to, release process definitions/procedures | N/A | Can be assessed by the user organisation in an audit. |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 12 (15) |

H. Support / Maintenance

| | Item | Yes/No | Comments |
|-----|--|--------|---|
| H.1 | Explanation of support services (agreements, scope, procedures, support organization, responsibilities, provision locally/internally, use of third parties, maintenance of support agreements) | Yes | Service and Service Agreements are handled by the Labcrew organisation. Information on service agreements etc is available on the web site. |
| H.2 | Duration of guaranteed support (number of versions, minimum periods) | Yes | The general policy is: The current version is supported. Older versions are supported by upgrading to the latest version. Exceptions from this rule exist and are handled on a case by case basis. |
| H.3 | Provision of Help Desk (levels of service, hours of operation) | Yes | Handled on a regional level. Telephone support FOC during office hours (Sweden) Documentation is available over the web. Labcrew offers different levels of service agreements including 7/24 support. |
| H.4 | Fault reporting mechanism (logging, analysing, categorising, resolving, informing, closing, documenting, distribution, notification of other customers with/without support agreements) | Yes | Customer complaints are recorded and managed in CSSx, see Customer Feedback BMI Ref. no 70-5009-31, where a case is created and a contact person assigned. Status of each complaint can be viewed on-line by Amersham Biosciences support staff world wide. Notifications of faults are made through Information letters that are available on web site provided that the user register and has a system serial number available. |
| H.5 | Link between fault reporting mechanism and Change Control | | Fault reports in CSSx are reviewed by the product manager who then decides if and when a new release with its relating Change Control procedure should be initiated. |
| H.6 | Method of handling of customer complaints | Yes | See H4 |
| H.7 | Accuracy of, and conformance to, support process definitions/procedures | N/A | Can be assessed by the user organisation in an audit. |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 13 (15) |

I. Supporting Processes and Activities

| | Item | Yes/No | Comments |
|-----|--|--------|---|
| I.1 | <p>Documentation management (covering QMS and product/project documents):</p> <ul style="list-style-type: none"> - In accordance with QMS/Quality Plan - Following documentation standards - Indexed, organized - Reviews carried out prior to approval and issue - Reviews recorded, indexed, followed up and closed off (with supporting evidence) - Evidence of timely management action for reviews which remain open - Formal approvals recorded, meaning of approvals defined - Distribution controlled - Document history maintained - Removal of superseded/obsolete documents | Yes | <p>The On-line Lotus based Project Archive (PARC):</p> <ul style="list-style-type: none"> - Contains document templates - Indexes and organises documentation including unique document number. - Contains features for review and approval and to manage review comments. - All status changes on a document is logged - Previous versions are recorded in a separate database - Obsolete documents can be removed, special privileges needed |
| I.2 | <p>Software Configuration Management</p> <ul style="list-style-type: none"> - System for identifying, controlling and tracking every version of each software configuration item - System for recording the configuration of each release (i.e., which software configuration items and versions are used) - Identification of the point at which Change Control is applied to each software configuration item - Control of build tools and layered software products, including the introduction of new versions | Yes | <p>The version status of each element in the software release, including build tools, is defined in the Software Version Description Document (SVD)</p> <p>Microsoft SourceSafe is used to record and keep track of software versions during the development process</p> <p>As a general rule all software modules that have changed are re-tested. If only a small numbers of changes have been made a selective test plan for the specific changes can be defined in the SDP. This plan has to be approved by the line manager.</p> |
| I.3 | <p>Change Control covering software, hardware, documentation:</p> <ul style="list-style-type: none"> - All change requests formally logged, indexed and assessed - Rejected requests identifies as such, reasons documented, signed by those responsible and the originator informed - Changes authorized, documented, tested and approved prior to implementation (except for emergencies) - Emergency process definition/procedure documented covering reviewing, testing, approving, and recording - Impact of each change (on other items and on requirements for re-test) assessed and documented | Yes | <p>Change control of a released product is handled as a (small) project. The scope of the project is defined in the SDP.</p> <p>Changes in a running project are notified to PMG for decision as a PCCR.</p> <p>See also Sw Product care 70-5020-06.</p> |
| I.4 | <p>Security process definitions/procedures (physical access, logical access to accounts/software, virus controls)</p> | Yes | <p>Physical access is controlled by site operation and includes tokens and codes.</p> <p>Access to computers and network is password protected. Ref. Information Management Security Standards BMI ref no 70-5028-55</p> <p>Virus control is provided as a general service by IM Ref. IT Knowledge Base: Virus Protection Process Virus Protection – Service</p> |
| I.5 | <p>Backup and recovery process definitions/procedures (secure storage and handling of</p> | Yes | <p>Back-ups are made to a separate server environment. Archiving is done in two archives.</p> |

UNICORN 5.0 audit checklist



| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 14 (15) |

| | | | |
|-----|--|-----|---|
| | media, on-site, off-site, recovery procedure exercised) | | <p>Archives and back-up servers are on-site in different fire cells.</p> <p>Domino based applications, such as PARC are also replicated to a number of servers.</p> <p>Ref. IT Knowledge Base: Backup - service</p> |
| I.6 | Disaster recovery process definition/procedure (tried) and documented evidence of disaster recovery testing | Yes | <p>Recovery of data is done in the IM support process. Such events are recorded in the Support data base.</p> <p>Recovery test of complete back-ups are performed by IM on a quarterly basis.</p> |
| I.7 | Control of purchased items bought on behalf of user (e.g., computer hardware, layered software products), including associated packaging, user documentation, warranties | N/A | UNICORN is a software product. And includes no layered software products or hardware. |
| I.8 | Accuracy of, and conformance to, relevant process definitions/procedures | N/A | Can be assessed by the user organisation in an audit. |

| | |
|------------|----------------|
| edition AA | 257426975-S365 |
| page | 15 (15) |

Appendix Protein Separations Senior Management (January 2004)

