

# **The BlazeLIMS Family of Products**

## **Functional Specs V6.0**

These Functional Specs have been organized according to the workflow of a comprehensive laboratory that uses all the LIMS functions. Depending on the type of laboratory, some of the functions are not applicable. The document begins with a high level graphical representation of the workflow which is intended as a roadmap through the document. The set of features described are comprehensive of the ASTM E1578 Standard Guide For LIMS.

<b>THE BLAZELIMS FAMILY OF PRODUCTS .....</b>	<b>1</b>
<b>FUNCTIONAL SPECS V6.0 .....</b>	<b>1</b>
<b>WORKFLOW DIAGRAM.....</b>	<b>10</b>
<b>1. TESTING PROPOSAL/TEMPLATE .....</b>	<b>11</b>
1.1. CREATE TESTING PROPOSAL/TEMPLATE .....	11
1.2. UNIQUE LIMS NUMBER AUTOMATICALLY ASSIGNED TO EACH PROPOSAL .....	11
1.3. CONFIGURATION OF USER ENTRY FIELDS FOR TESTING REQUESTS .....	11
1.4. CONFIGURATION OF TESTS FOR TESTING REQUESTS.....	11
1.5. OTHER TASKS .....	11
1.6. CONFIGURATION OF WORKFLOW FOR A TESTING REQUEST .....	11
1.7. CONFIGURATION OF NOTIFICATION RULES.....	11
1.8. DOCUMENT MANAGEMENT .....	11
1.9. ESTIMATING .....	11
1.10. REPORTS.....	11
1.11. TEST SCHEDULING.....	12
<b>2. TESTING REQUESTS .....</b>	<b>12</b>
2.1. CREATE TESTING REQUESTS.....	12
2.2. UNIQUE LIMS NUMBER AUTOMATICALLY ASSIGNED TO EACH TESTING REQUEST .....	12
2.3. ENTRY OF TEST REQUEST DESCRIPTION FIELDS.....	12
2.4. USER ENTRY SAMPLE DESCRIPTION FIELDS.....	12
2.5. SPECIFICATION OF TESTS FOR TESTING REQUESTS.....	12
2.6. OTHER TASKS .....	12
2.7. BARCODE LABELING .....	12
2.8. WORKFLOW FOR A TESTING REQUEST .....	13
2.9. BACKLOG .....	13
2.10. NOTIFICATIONS .....	13
2.11. REVIEW .....	13
2.12. APPROVAL .....	13
2.13. PUBLISH .....	13
2.14. ESTIMATES, SHIPPING PAPERS, INVOICES .....	13
2.15. DOCUMENT MANAGEMENT .....	13
2.16. REPORTS.....	14
2.17. TEST SCHEDULING.....	14
2.18. EXTERNAL SYSTEM INTERFACES .....	14
2.19. QUERY .....	14
<b>3. SAMPLE LOGIN.....</b>	<b>14</b>
3.1. SINGLE SAMPLE LOGIN .....	14
3.2. SAMPLE CONTAINER MANAGEMENT .....	14
3.3. UNIQUE LIMS NUMBER AUTOMATICALLY ASSIGNED TO EACH SAMPLE .....	15
3.4. USER ENTRY SAMPLE DESCRIPTION FIELDS.....	15
3.5. USER ENTRY TESTING REQUIREMENTS .....	15
3.6. GROUP OR BATCH SAMPLE LOGIN .....	15
3.7. UNIQUE LIMS NUMBER AUTOMATICALLY ASSIGNED TO EACH BATCH .....	16
3.8. BARCODE LABELING .....	16
3.9. ROUTINE SCHEDULE LOGIN.....	16
3.10. CREATE LOGIN SCHEDULE BY PATTERN .....	16
3.11. CREATE LOGIN SCHEDULE BY CALENDAR MARKING (STABILITY SHELF LIFE) .....	16

3.12.	LIST SCHEDULE BY LOGIN TEMPLATE (TABULAR AND CALENDAR IMAGE) .....	16
3.13.	LIST SCHEDULE BY TEST (TABULAR AND CALENDAR IMAGE) .....	16
3.14.	LOGIN FROM EXTERNAL SYSTEMS OR FILES .....	17
3.15.	LIMS RESAMPLE LOGIN .....	17
3.16.	LIMS RETEST LOGIN.....	17
3.17.	EVENT TRIGGER LOGIN.....	17
3.18.	MODIFY TESTS ASSIGNED TO SAMPLE DURING LOGIN .....	17
3.19.	AD-HOC LOGIN AND TEST ASSIGNMENTS.....	17
3.20.	REGISTER SAMPLE RECEIPT FOR PRE-LOGGED SAMPLE .....	17
3.21.	ADD OR DELETE TESTS OR PROFILES FROM LOGGED IN SAMPLE .....	17
3.22.	USER DEFINABLE LOGIN METHODS .....	17
3.23.	USER DEFINABLE LOGIN SCREENS .....	18
3.24.	EASE OF LOGIN.....	18
3.25.	LOGIN REPORTS.....	18
<b>4.</b>	<b>LABELS .....</b>	<b>18</b>
4.1.	PRINT CONTAINER LABEL (WITH AND WITHOUT BARCODES).....	18
4.2.	PRINT CONTAINER REQUIREMENTS REPORT FROM SCHEDULE .....	18
4.3.	PRINT LABELS FROM LOGGED IN SAMPLES (WITH BAR CODES) .....	18
4.4.	PRINT SHIPPING LABELS.....	18
4.5.	PRINT LABELS FROM SCHEDULE .....	18
4.6.	PRINT SAMPLE RECEIPT .....	19
4.7.	PRINT SAMPLING ROUTE LIST FROM SCHEDULE .....	19
4.8.	FLASK LABELS (REMOVABLE) .....	19
4.9.	USER DEFINABLE LABEL FORMATS .....	19
4.10.	WHMIS WORKPLACE LABELS .....	19
4.11.	EASE OF LABEL FUNCTIONS .....	19
4.12.	CURRENT LABEL PRINTERS .....	19
<b>5.</b>	<b>SAMPLE DISTRIBUTION AND TRACKING .....</b>	<b>19</b>
5.1.	TRACKING .....	19
5.2.	DISTRIBUTION LISTS .....	19
5.3.	CHAIN OF CUSTODY.....	19
5.4.	SAMPLE ROUTING.....	19
5.5.	SAMPLE SHIPPING.....	19
5.6.	SAMPLE STORAGE AND RETRIEVAL.....	20
5.7.	SAMPLE STORAGE INVENTORY MANAGEMENT .....	20
5.8.	SAMPLE DISPOSITION / DISPOSAL MANAGEMENT .....	20
5.9.	ON-LINE ACCESS TO SAMPLE DISTRIBUTION, STORAGE & SAFETY INFORMATION .....	20
<b>6.</b>	<b>ASSIGNING WORK.....</b>	<b>20</b>
6.1.	GROUPING TESTS BY QC BATCH OR RUN .....	20
6.2.	SELECT AND ASSIGN TASKS.....	20
6.3.	PRINT INSTRUMENT BACKLOG FROM ACTIVE SAMPLES .....	21
6.4.	PRINT ANALYST BACKLOG .....	21
6.5.	PRINT BACKLOG OF EXPIRING SAMPLES IN TIME ORDER .....	21
6.6.	INSTRUMENT SEQUENCE OR CONTROL FILE GENERATION.....	21
6.7.	USER DEFINABLE WORK ASSIGNMENT METHODS .....	22
6.8.	ANALYST WORKSHEETS .....	22
6.9.	SAMPLE PREPARATION / ELN .....	22
6.10.	PREP BATCHING .....	22
6.11.	REAGENT MANAGEMENT.....	23

6.12.	STANDARDS MANAGEMENT .....	23
6.13.	INSTRUMENT MANAGEMENT.....	23
6.14.	PERSONNEL MANAGEMENT .....	23
6.15.	PREP TEMPLATING.....	23
6.16.	PRODUCE WORKSHEETS .....	23
<b>7.</b>	<b>DATA CAPTURE – ENTERING DATA &amp; INFORMATION .....</b>	<b>23</b>
7.1.	MANUAL KEYBOARD DATA ENTRY .....	23
7.2.	AUTOMATED CAPTURE VIA SCREENS .....	24
7.3.	AUTOMATED INSTRUMENT DATA ENTRY .....	24
7.4.	DATA IMPORT.....	26
<b>8.</b>	<b>SPECIFICATION CHECKING.....</b>	<b>26</b>
8.1.	ONE LEVEL .....	26
8.2.	TWO LEVELS .....	26
8.3.	THREE LEVELS .....	26
8.4.	MISSING SPECIFICATIONS .....	26
8.5.	APPROXIMATE SPECIFICATION CHECKING <, > .....	26
8.6.	LIMIT OF INSTRUMENT DETECTION ISSUES.....	26
8.7.	USER DEFINABLE SPECIFICATION CHECKING FUNCTIONS .....	27
8.8.	AD-HOC SPECIFICATION DEFINITION POST LOGIN .....	27
8.9.	SPECIFICATIONS BASED ON TEST RESULTS.....	27
8.10.	WARNING TO USER FOR OUT OF SPECIFICATION (AUDIBLE, SCREEN MESSAGE, COLOR, FLAG).....	27
8.11.	CUSTOM USER DEFINED ALGORITHMS FOR SPECIFICATION CHECKING .....	27
8.12.	SPECIFICATION MANAGEMENT.....	27
<b>9.</b>	<b>CALCULATIONS.....</b>	<b>27</b>
9.1.	INTER TEST.....	27
9.2.	INTRA TEST .....	27
9.3.	INTRA SAMPLE .....	27
9.4.	INTER SAMPLE .....	27
9.5.	DESCRIPTIVE STATISTICS.....	28
9.6.	ADVANCED MATH FUNCTIONS.....	28
9.7.	USER DEFINED FUNCTIONS.....	28
9.8.	LINKS TO PRIOR RESULTS .....	28
9.9.	TRIGGER/EVENT FUNCTIONS .....	28
9.10.	LIBRARY OF MATH SUBROUTINES .....	28
9.11.	SAMPLE PREPARATION FACTORS .....	28
9.12.	LINEAR CALIBRATION & METHOD-OF-ADDITION CALCULATIONS .....	28
<b>10.</b>	<b>QUALITY CONTROL MONITORING.....</b>	<b>28</b>
10.1.	QC TEMPLATES.....	28
10.2.	AUTOMATIC GENERATION OF CONTROL CHARTS .....	28
10.3.	AUTOMATIC STATISTICAL CONTROL.....	29
10.4.	AUTOMATIC TREND ANALYSIS.....	29
10.5.	AUTOMATIC CALCULATION OR % ACCURACY OF CONTROLS .....	29
10.6.	AUTOMATIC CALCULATION OF % SPIKES .....	29
10.7.	AUTOMATIC CALCULATION OF % RECOVERED .....	29
10.8.	AUTOMATIC CALCULATION OF % DIFFERENCE OF DUPLICATES.....	29
10.9.	INTERNAL AUDITS.....	29
<b>11.</b>	<b>DATA ANALYSIS AND GRAPHICS .....</b>	<b>29</b>

11.1.	DATA ANALYSIS.....	29
11.2.	2D CONTROL CHARTS, TREND CHARTS, PARTICLE SIZE HISTOGRAMS, AND CHROMATOGRAPHS. ....	29
11.3.	3D .....	29
<b>12.</b>	<b>DATA EDIT / CORRECTION.....</b>	<b>29</b>
12.1.	EDIT SAMPLE INFORMATION .....	30
12.2.	EDIT TEST RESULTS .....	30
12.3.	AUDIT TRAIL CHANGES (KEEP ORIGINAL DATA PLUS INFO ON CHANGES).....	30
12.4.	FORCE COMMENTS FOR ALL CHANGES .....	30
12.5.	CHANGE ACTIONS.....	30
12.6.	EASE OF CHANGES .....	30
12.7.	AUTOMATIC DATA TRANSFER CHANGES.....	30
<b>13.</b>	<b>CHECKING, REVIEWING AND APPROVING RESULTS .....</b>	<b>30</b>
13.1.	CHECK / VERIFY TESTS.....	30
13.2.	REVIEW / VERIFY TESTS .....	30
13.3.	APPROVE / VERIFY TESTS .....	30
13.4.	RESCHEDULE A TEST .....	30
13.5.	RESCHEDULE A SAMPLE.....	30
13.6.	APPROVE SAMPLES .....	30
13.7.	COMMUNICATE STATUS TO EXTERNAL SYSTEMS .....	31
13.8.	USER DEFINABLE REVIEW AND APPROVAL METHODS .....	31
13.9.	APPROVAL NOTIFICATION .....	31
<b>14.</b>	<b>REPORTING RESULTS.....</b>	<b>31</b>
14.1.	SINGLE SAMPLE REPORTS.....	31
14.2.	GROUP ANALYSIS REPORTS .....	31
14.3.	REPORT PREVIEWS .....	31
14.4.	CERTIFICATE OF ANALYSIS REPORTS .....	32
14.5.	GRAPHICAL RESULTS REPORTS .....	32
14.6.	CHAIN OF CUSTODY REPORT.....	32
14.7.	LINK TO E-MAIL REPORT DISTRIBUTION.....	32
14.8.	ABILITY TO FAX .....	32
14.9.	USER DEFINABLE REPORTS .....	32
14.10.	AD-HOC REPORTS .....	32
14.11.	REPORT TOOLS (STANDARD OR PROPRIETARY).....	32
14.12.	EXPORT DATA SETS (SMALL AND LARGE) TO EXTERNAL SYSTEMS.....	32
14.13.	AUDIT TRAIL REPORTS .....	32
14.14.	COMMENT REPORTS .....	32
14.15.	CONTROL CHART REPORTS.....	33
14.16.	REPORTS TO FILES (DISKS) .....	33
14.17.	CONTROL OF AUTOMATIC PRINTING .....	33
14.18.	CONTRACT LABORATORY PROGRAM REPORTS & DISKETTE.....	33
14.19.	AD HOC QUERY .....	33
<b>15.</b>	<b>MANAGING LAB OPERATIONS .....</b>	<b>33</b>
15.1.	SAMPLE STATUS REPORTS.....	33
15.2.	WORKLOAD REPORTS .....	33
15.3.	OVERDUE REPORTS .....	33
15.4.	INSTRUMENT LOADING REPORTS.....	33
15.5.	INSTRUMENT CALIBRATION MANAGEMENT .....	33
15.6.	PERSONNEL LOADING REPORTS.....	34

15.7.	ACCOUNTING REPORTS .....	34
15.8.	QUALITY ASSURANCE REPORTS.....	34
15.9.	CAPABILITY CATALOG .....	34
15.10.	TRANSACTION LOG LISTING AND MAINTENANCE .....	34
15.11.	INVENTORY MANAGEMENT .....	34
15.12.	INSTRUMENT CALIBRATION REPORTS .....	34
15.13.	NEW INSTRUMENT REPORTS (BENCHMARKS).....	34
15.14.	LATE CALIBRATIONS.....	34
15.15.	EXCEPTION REPORTS.....	34
15.16.	REAGENT & STANDARDS INVENTORY REPORTS .....	34
15.17.	TRAINING .....	35
15.18.	APPROVED SUPPLIER LIST .....	35
15.19.	AUTOMATIC EVENT SCHEDULING .....	35
15.20.	ENVIRONMENTAL MONITORING.....	35
<b>16.</b>	<b>DOCUMENT MANAGEMENT .....</b>	<b>35</b>
16.1.	CAPTURE, STORE, VIEW AND EDIT DOCUMENTS.....	35
16.2.	DOCUMENT STORAGE CONTEXT .....	35
16.3.	MANAGED DOCUMENTS.....	35
16.4.	LINKED DOCUMENTS.....	36
<b>17.</b>	<b>ALARMS AND ALERTS.....</b>	<b>36</b>
17.1.	ALARM AND ALERT INFRASTRUCTURE.....	36
17.1.	ALERT CONFIGURATION .....	36
17.2.	NOTIFICATIONS .....	36
<b>18.</b>	<b>CAPA.....</b>	<b>36</b>
18.1.	CREATE, AND MANAGE QUALITY EVENTS.....	36
18.2.	TEMPLATE CORRECTIVE AND PREVENTIVE ACTIONS.....	36
18.3.	AUTOMATIC CREATION OF QUALITY EVENTS.....	36
<b>19.</b>	<b>ELN .....</b>	<b>36</b>
19.1.	QC ELN .....	37
19.2.	QC ELN INTEGRATION .....	37
19.3.	R&D ELN.....	37
<b>20.</b>	<b>CUSTOMER MANAGEMENT .....</b>	<b>37</b>
20.1.	CUSTOMER MASTER .....	37
20.2.	INTEGRATION WITH LIMS/LIS FUNCTIONS .....	37
20.3.	RESULTS AND NOTIFICATIONS .....	37
<b>21.</b>	<b>CASE MANAGEMENT .....</b>	<b>37</b>
21.1.	PATIENT CENTRIC .....	37
21.2.	INTEGRATION WITH LIMS/LIS FUNCTIONS .....	37
21.3.	HIPAA SUPPORT .....	37
<b>22.</b>	<b>SYSTEM MAINTENANCE .....</b>	<b>38</b>
22.1.	SYSTEM DATA MAINTENANCE .....	38
22.2.	ARCHIVING RESULT DATA PROCESS DATA.....	38
22.3.	RESULT EXPORT DATA.....	38
<b>23.</b>	<b>INFORMATION ACCESS – ON-LINE.....</b>	<b>38</b>

23.1.	SOPs.....	38
23.2.	METHOD DEVELOPMENT.....	38
23.3.	METHOD VALIDATION .....	38
23.4.	SUPPORTING TECHNICAL INFORMATION .....	38
23.5.	HISTORICAL QA DATA.....	38
<b>24.</b>	<b>DATABASE STRUCTURE .....</b>	<b>38</b>
24.1.	FLAT FILE .....	38
24.2.	RELATIONAL .....	38
24.3.	CLIENT SERVER / DISTRIBUTED DATABASE .....	39
24.4.	MATCH TO CURRENT INFORMATION STRUCTURE / RELATIONSHIPS.....	39
24.5.	MATCH TO CURRENT LABORATORY MATERIAL/TEST/SPECIFICATION STRUCTURE .....	39
24.6.	LIMS SAMPLE / RESULT DATA BASE STRUCTURE: ASSESS FIT TO LABORATORY .....	39
<b>25.</b>	<b>DATA INTEGRITY .....</b>	<b>39</b>
25.1.	TRANSACTIONAL INTEGRITY .....	39
25.2.	DATA INTEGRITY REPORT .....	39
25.3.	DATA RECOVERY AFTER FAULT .....	39
25.4.	DATA INTEGRITY DURING CONCURRENT DEVELOPMENT .....	39
<b>26.</b>	<b>PROGRAM STRUCTURE .....</b>	<b>40</b>
<b>27.</b>	<b>LIMS PERFORMANCE .....</b>	<b>40</b>
<b>28.</b>	<b>DATABASE TOOLS .....</b>	<b>40</b>
28.1.	USER DEFINABLE TABLES .....	40
28.2.	USER DEFINABLE FIELDS .....	40
28.3.	USER DEFINABLE INDEXES.....	40
28.4.	USER DEFINABLE FIELD EXPRESSIONS.....	41
28.5.	USER DEFINABLE FIELD AUTHORITIES BY DATA TYPE, CATEGORY, GROUP, USER .....	41
28.6.	IMPORT / EXPORT LIMS MODULES (LOGIN/RESULT ENTRY METHODS, SCREENS FORMATS, REPORTS) .....	41
28.7.	AUTOMATIC RESTRUCTURE OF OLD DATA INTO NEW STRUCTURE .....	41
<b>29.</b>	<b>CONFIGURATION TOOLS (CONFIGURATION OF LIMS TO MEET WORK FLOW REQUIREMENTS).....</b>	<b>41</b>
29.1.	MATERIAL DEFINITIONS .....	41
29.2.	TEST DEFINITIONS .....	41
29.3.	RESULT/OBSERVATION DEFINITION .....	42
29.4.	ALGORITHM DEFINITION .....	42
29.5.	TOOLS FOR BUILDING ALGORITHMS .....	42
29.6.	PROFILE DEFINITION.....	42
29.7.	TIME STUDY DEFINITION .....	42
29.8.	SPECIFICATION DEFINITION .....	42
29.9.	REVISION CONTROL .....	42
29.10.	AUDIT TRAIL CHANGES .....	42
29.11.	CONFIGURATION REPORTS.....	42
29.12.	TIME REQUIRED TO ADD ONE LIMS MATERIAL WITH ONE TEST AND SPECIFICATION.....	43
29.13.	TIME REQUIRED TO ADD ON MATERIAL WITH 10 TESTS AND SPECIFICATIONS .....	43
29.14.	TIME REQUIRED TO INTERFACE INSTRUMENTS TO LIMS .....	43
29.15.	CORRECT ASSOCIATION OF SPECIFICATION WITH HISTORICAL RECORDS AFTER A CHANGE IN SPECIFICATION .....	43
29.16.	CORRECT ASSOCIATION OF INFORMATION WITH HISTORICAL RECORDS AFTER A CHANGE IN REFERENCE INFORMATION .....	43
29.17.	MULTI-LINGUAL.....	43
<b>30.</b>	<b>NUMERICAL REPRESENTATION .....</b>	<b>43</b>

30.1.	INTERNAL REPRESENTATION OF NUMERIC VALUES.....	43
30.2.	ROUNDING ISSUES .....	43
30.3.	COMPARISON OPERATORS (<,>, +,-) .....	44
30.4.	DATA TYPES .....	44
30.5.	LOGICAL .....	44
30.6.	DATE .....	44
<b>31.</b>	<b>STRING MANIPULATION FUNCTIONS .....</b>	<b>44</b>
<b>32.</b>	<b>AUDIT TRAILS.....</b>	<b>44</b>
32.1.	RESULT LEVEL EDITS .....	44
32.2.	SAMPLE LEVEL EDITS.....	44
32.3.	LIMS DATABASE STRUCTURE EDITS .....	44
32.4.	TEST STRUCTURES .....	45
32.5.	SPECIFICATIONS.....	45
32.6.	LIMS METHODS.....	45
<b>33.</b>	<b>CHANGE CONTROL.....</b>	<b>45</b>
33.1.	CODE CHANGE.....	45
33.2.	STATIC TABLE AND SPECIFICATION.....	45
33.3.	LIMS METHODS (LOGIN, RESULT ENTRY...) .....	45
33.4.	LIMS REPORTS .....	45
33.5.	SECURITY .....	45
<b>34.</b>	<b>HARDWARE .....</b>	<b>45</b>
<b>35.</b>	<b>WARRANTY.....</b>	<b>45</b>
<b>36.</b>	<b>USER FRIENDLY INTERFACE .....</b>	<b>46</b>
36.1.	USER FRIENDLY CHARACTERISTICS.....	46
36.2.	CUSTOMER FEEDBACK.....	46
<b>37.</b>	<b>SYSTEM RELIABILITY AND MAINTENANCE REQUIREMENTS .....</b>	<b>46</b>
37.1.	RELIABILITY / REDUNDANCY.....	46
37.2.	MEAN TIME BETWEEN FAILURES .....	46
37.3.	MANUAL WORK FLOW PROVISIONS DURING FAILURE .....	46
37.4.	SELF-TESTS AND DIAGNOSTICS.....	46
37.5.	REPAIR / REPLACE POLICY (SOFTWARE ONLY) .....	46
37.6.	TIME TO REPAIR (SOFTWARE ONLY).....	47
37.7.	MAINTENANCE TRAINING LEVEL REQUIRED .....	47
37.8.	SOFTWARE MAINTENANCE & UPDATES .....	47
<b>38.</b>	<b>SECURITY .....</b>	<b>47</b>
38.1.	LIMS BY GROUP.....	47
38.2.	LIMS BY USER .....	47
38.3.	LIMS BY DATA TYPE .....	48
38.4.	LIMS BY FIELD .....	48
38.5.	BY LIMS FUNCTION.....	48
38.6.	BY OS SYSTEM (MINI/LAN) .....	48
38.7.	BY FACILITY (PHYSICAL SECURITY).....	48
38.8.	BY NETWORK (WAN) .....	48
38.9.	BY ELECTRONIC IDENTIFICATION (PASSWORDS, BADGES, BAR CODES) .....	48

38.10.	BY ELECTRONIC SIGNATURE (BIOMETRIC VERIFICATION, I.E. RETINA SCAN).....	48
38.11.	AUTOMATIC TERMINAL TIME OUT.....	48
38.12.	ENCRYPTION .....	48
<b>39.</b>	<b>VENDOR RATING.....</b>	<b>48</b>
39.1.	VOICE SUPPORT .....	48
39.2.	MODEM SUPPORT.....	48
39.3.	HELP DESK SUPPORT.....	49
39.4.	INSTALLATION SUPPORT.....	49
39.5.	DOCUMENTATION .....	49
39.6.	ESTABLISHED SOFTWARE DEVELOPMENT STANDARDS.....	49
39.7.	FORM CHANGE CONTROL .....	49
39.8.	SOFTWARE REVISION CONTROL.....	49
39.9.	SOFTWARE PORTABILITY.....	49
39.10.	ACCESS TO SOURCE CODE.....	49
39.11.	QUALITY AND SKILLS OF STAFF.....	49
39.12.	QUANTITY OF SUPPORT STAFF FOR CUSTOMER SUPPORT .....	49
39.13.	QUANTITY OF STAFF DEDICATED TO R&D ON FUTURE LIMS FUNCTIONS .....	49
39.14.	ABILITY OF VENDOR TO APPLY NEW TECHNOLOGY TO LIMS PRODUCT.....	49
39.15.	FINANCIAL STABILITY.....	49
39.16.	NUMBER OF LIMS INSTALLED.....	49
39.17.	NUMBER OF YEARS IN THE LIMS BUSINESS.....	49
39.18.	MEET GMP/GALP, NELAC, 21CFR OR OTHER REGULATORY REQUIREMENTS.....	50
39.19.	PROBLEM RESOLUTION TIME .....	50
39.20.	SALES / SUPPORT LOCATION .....	50
<b>40.</b>	<b>COST .....</b>	<b>50</b>
<b>41.</b>	<b>LINKS TO GENERAL PURPOSE TOOLS.....</b>	<b>50</b>
41.1.	WORD PROCESSING.....	50
41.2.	SPREADSHEET .....	50
41.3.	POP-UP CALCULATOR(S).....	50
41.4.	STATISTICAL ANALYSIS.....	50
41.5.	GRAPHIC PRESENTATION.....	50
41.6.	REPORTS.....	50
41.7.	EMAIL .....	51



Feature	BlazeLIMS Capability
<b>1. Testing Proposal/Template</b>	
1.1. Create Testing Proposal/Template	Using the BlazeLIMS Work Request Spec screen, a comprehensive description of a testing proposal or template for testing requests called a work request spec can be created.
1.2. Unique LIMS number automatically assigned to each proposal	BlazeLIMS can assign a unique identification to each work request spec, or it can be appropriately named for use as a template. The format of this identifier is user definable and highly flexible.
1.3. Configuration of user entry fields for testing requests	More than 20 description fields such as purpose, customer, project, etc. can be specified. These specifications determine the parameters to be requested in a testing request, their formats, and possible default values.
1.4. Configuration of tests for testing requests	A set of sample types and associated testing can be specified for use as defaults or as a menu of sample types and tests when creating a testing request. These may be configured to provide a test selection screen that is test group, test, or analyte centric, or may provide a default set of testing to be adjusted for each request, providing a flexible, powerful, and user friendly system for any kind of test suite or testing request from the highly structured and repetitive to the completely ad-hoc.
1.5. Other Tasks	A wide variety of tasks may be specified in addition to the most common task of samples. Other tasks include Make, Fill, Ship, Package, Screen, Uniformity, Dissolution, and more. These features allow the work request system to be used as a full-fledged production batch recipe/management system.
1.6. Configuration of workflow for a testing request	Workflow for associated testing request may be specified to include rules for processing, barcode labeling, report printing, life cycle steps and much more.
1.7. Configuration of notification rules	Rules for providing notifications at key events in the life of associated testing requests may be specified. A powerful and flexible mechanism for determining addressees based on roles is available to reduce configuration difficulty and redundancies.
1.8. Document management	Multiple documents of any type associated with the work request specification may be captured and managed by a system of version control through the steps of review, approval and activation. All documents are stored on the server for ease of backup and recall.
1.9. Estimating	Estimates may be generated and output in a proposal document based on a wide variety of costing paradigms which can involve base test pricing, volume pricing customer specific pricing, and proposal specific pricing.
1.10. Reports	Various reports are available to output information about a work request specification. These are based on Crystal Reports, Excel or Word and are thus highly flexible and user configurable. Also, reports for associated testing requests may be customized for a specific customer or for a specific work request specification.

Feature	BlazeLIMS Capability
1.11. Test scheduling	Calendar or interval based schedules may be defined to create specific testing requests according to pre-determined rules.
<b>2. Testing Requests</b>	
2.1. Create Testing Requests	Using any of several work request entry screens (test group, test, analyte centric), either Windows or browser based, a testing request may be created. These screens are most often used in conjunction with a work request spec or template as described above, which acts to configure the screen for ease of use and error free entry.
2.2. Unique LIMS number automatically assigned to each testing request	BlazeLIMS can assign each testing request a unique work request number. The format of this number is user definable and highly flexible. Optionally a number assigned by another system may be entered.
2.3. Entry of test request description fields	More than 20 description fields such as purpose, customer, project, etc. can be entered, their appearance, formats and default values specified in the associated work request specification to provide a highly configurable and easy to use system that requests only the fields needed
2.4. User entry sample description fields	More than 15 description fields (e.g. user id, lot, etc.) are available for entry to describe the samples. Their appearance, formats, default values, etc. may be specified in the work request spec to provide a highly configurable and easy to use system that requests only the fields needed.
2.5. Specification of tests for testing requests	Sample and testing descriptions may be entered or selected from menus in a flexible and highly usable fashion, as determined and defined in the work request specification. The entry screens are highly optimized to a particular kind of testing suite and the associated work request specification for maximum utility and ease of entry with minimum redundancy. This can range from a fixed set of samples and tests that are repeated over and over with little manual entry to an ad-hoc set of samples and test selected from a large menu of available services organized on the basis of testing groups, tests, or analytes.
2.6. Other Tasks	A wide variety of tasks may be specified in addition to the most common task of samples. Other tasks include Make, Fill, Ship, Package, Screen, Uniformity, Dissolution, and more. These features allow the Work request system to be used as a full-fledged production batch recipe/management system.
2.7. Barcode labeling	Barcode labels may be printed for the overall test request and/or for the samples/containers as they are pre-logged. Barcode label formats are highly configurable and flexible to include any desired information.

Feature	BlazeLIMS Capability
2.8. Workflow for a testing request	Workflow for the testing request is executed over a life cycle including multiple stages or states allowing verification, activation, execution, review, approval, and final publishing, as specified on a system wide basis or in the associated work request specification. Each workflow step can involve notifications, printing of reports, electronic signatures, etc. and the time and user associated with a change is tracked. Some changes are user initiated, typically via a pushbutton (e.g. Activate) and some are automatically initiated based on changes in the associated sample states (e.g. all samples approved) to provide a powerful and instantaneous display of the overall state of the testing request, including any indication of out-of-spec results.
2.9. Backlog	A screen and reports are available to provide a comprehensive and easy to use backlog of work requests to assist in managing and directing work at the work request and work request task level.
2.10. Notifications	Notifications may be automatically triggered at key events in the life of testing requests as specified in the work request spec or as entered when creating the work request. A powerful and flexible mechanism for determining addressees is available based on roles to reduce configuration difficulty and redundancies.
2.11. Review	Work requests may be reviewed, usually by taking advantage of a summary report. This may be used as the lab review step. The requirement to review a work request may be specified by the work request template and may be an electronic signature event.
2.12. Approval	Work requests may be approved, usually by taking advantage of an approval report. This may be used as the QA approval step. The requirement to review a work request may be specified by the work request template and may be an electronic signature event.
2.13. Publish	The official publishing (release/transmittal) of work requests may occur as part of the approval step or as a separate step. Reports may be automatically distributed via export to a customer based folder for display by the BlazeWebServer or other web applications, by e-mail or by fax.
2.14. Estimates, Shipping Papers, Invoices	Estimates and invoices may be generated and output in a document based on a wide variety of costing paradigms which can involve base test pricing, volume pricing and customer specific pricing, and proposal specific pricing. Invoices may be issued or the information sent to another invoicing system. Packing and shipping papers may be printed using Crystal Reports, Excel or Word and are thus highly flexible and user configurable.
2.15. Document management	Multiple documents of any type associated with the work request may be captured and managed by a system of version control. All documents are stored on the server for ease of backup and recall.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
2.16. Reports	Various reports are available to summarize information about a work request. These are based on Crystal Reports, Excel or Word and are thus highly flexible and user configurable. Also, reports for testing requests may be customized for a specific customer or for a specific work request specification. Reports may be issued by pushbutton, by event, included in notifications, etc. Typical reports are COC, receipt, worksheet, summary, approval COA, etc.
2.17. Test scheduling	Comprehensive scheduling of work request tasks (samples, make, fill, etc.) is available to compute duration and start and end times based on ordering and duration rules, and run type (24 hour, 8 hour, etc.) An OLE linkage to Microsoft Project for export/import is available to provide graphical presentation, reports, resource assignment, work days, etc. This scheduling is propagated down to the scheduling of sample, aliquots, etc.
2.18. External System Interfaces	Test requests may be automatically created and filled in based on messages received from external systems (e.g. ERP, customer systems, etc.) The input formats are highly flexible and may be in text, CSV, Excel, xml, or other formats. Messages may be produced and sent to external systems for invoicing, COA, release, etc. The BlazeWeb Server provides these functions via web services.
2.19. Query	A structured query mechanism is available to find work requests satisfying a particular set of criterion. A comprehensive set of reports are available to provide structures information about work requests. In addition, Hunter For BlazeLIMS provides a user friendly, flexible ad-hoc, web based general query mechanism to produce any sort of dataset which can be exported to excel, etc. Queries may be saved and reused.
<b>3. Sample Login</b>	
3.1. Single Sample Login	Using the BlazeLIMS Log Sample screen, a single sample can be logged, most often done in conjunction with a comprehensive template capability. Templates are used to pre-configure the screen for fields, formats, requirements, default values, default testing, etc. They may be used to reduce manual input to an absolute minimum and to insure required data is properly entered. The net result is a sample login step for routine samples that usually requires the entry of only one or two field values.
3.2. Sample Container Management	A sample may be logged with multiple containers of different types associated with the methods to be run, labs to run the methods, kinds of container, etc. Containers may be identified, labeled and tracked comprehensively with complete COC in the same fashion as samples. This provides a powerful mechanism to manage and enforce requirements on container type, conditions, preservatives, routing in the lab, shipping to outside labs and much more that depends on the testing to be performed.

Feature	BlazeLIMS Capability
3.3. Unique LIMS number automatically assigned to each sample	BlazeLIMS assigns each sample a unique Sample Log Number. The format of this number is user definable and highly flexible. Optionally a number assigned by another system may be entered. Containers are assigned the Sample Log Number with a letter suffix.
3.4. User entry sample description fields	BlazeLIMS' user entry sample description fields include sample type, sample id, sample lot number, sample collection number, product, area, client, matrix, sampling point, project, hazards, disposal, patient, protocol, material, customer, and customer site the site fields, all of which may be renamed, reused, and reconfigured in or out of the entire system or on or off the screen based on sample type. There are 10 additional general purpose fields that may be configured to any data type and format. Consequently no costly customization is required to handle any and all needs for sample identification.
3.5. User entry testing requirements	<p>The BlazeLIMS sample login screen usually begins with a set of tests specified in a template as the default for a given kind of sample or situation (beginning of shift, etc.) Alternatively, it can allow for selection of test form a dropdown list for more ad-hoc situations.</p> <p>Variations from the default testing may be achieved by deleting pending tests, adding pending tests, or changing tests before actually logging the sample. Adjustments may be made at the test (method) level or at the individual analyte level within a method. All changes are enforced to follow the configured rules.</p>
3.6. Group or Batch Sample Login	<p>The BlazeLIMS sample login screen allows logging of multiple samples of the same type with different identifiers in one operation.</p> <p>BlazeLIMS provides a screen for logging a set of samples of different types to handle needs such as an entire production run, a collection of lab environmental samples, a sample collection route, a set of instrument calibrations, etc. This feature includes production of COC, routing slip, labels, worksheets, etc. Logging may be manually requested, or a comprehensive interval or calendar schedule configured to provide automatic logging according to comprehensive business rules.</p> <p>BlazeLIMS includes a work request screen for submitting testing requests involving multiple samples with configured or ad-hoc testing requirements Templates may be defined to assist in routine use. See section 1.</p> <p>The QC batch function performs batch logging of QC samples and samples for uniformity and dissolution studies.</p> <p>The Stability module performs automatic batch logging of samples for stability picking.</p> <p>Samples may be automatically logged when BlazeInventory materials are created or received when the materials are to be tested.</p>

Feature	BlazeLIMS Capability
3.7. Unique LIMS number automatically assigned to each batch	BlazeLIMS assigns a unique collection, work request or QC batch number where desired. The format of this number is user definable and highly flexible.
3.8. Barcode labeling	Barcode labels may be printed for the overall sample and/or for the containers and aliquots as they are pre-logged or received. Barcode label formats are highly configurable and flexible to include any desired information.
3.9. Routine Schedule Login	BlazeLIMS includes a sample autologger for logging routine samples according to a comprehensive interval or calendar schedule, configured according to comprehensive business rules. It includes the ability to vary the tests to be run (test scheduling) for each sampling within the overall schedule. It takes into account a comprehensive but easily configured set of rules involving day of week, day of month, week of month, month of year, holidays and more, allowing for an optimal scheduling based on anticipated work loading.
3.10. Create Login Schedule by Pattern	BlazeLIMS includes a sample autologger for logging routine samples according to a comprehensive interval or calendar schedule, configured according to comprehensive business rules. It includes the ability to vary the tests to be run (test scheduling) for each sampling within the overall schedule. It takes into account a comprehensive but easily configured set of rules involving day of week, day of month, week of month, month of year, holidays and more, allowing for an optimal scheduling based on anticipated work loading.
3.11. Create Login Schedule by calendar marking (stability shelf life)	<p>BlazeLIMS includes a sample autologger for logging routine samples according to a comprehensive interval or calendar schedule, configured according to comprehensive business rules. It includes the ability to vary the tests to be run (test scheduling) for each sampling within the overall schedule. It takes into account a comprehensive but easily configured set of rules involving day of week, day of month, week of month, month of year, holidays and more, allowing for an optimal scheduling based on anticipated work loading.</p> <p>BlazeLIMS provides a Stability module for managing stability shelf life studies. The stability protocol allows the user to define draw schedules in intervals of days, weeks, and months with associated variations in testing for each draw. The system automatically adjusts for holidays and weekends, and allows for preference to lower volume days taking allowed slack into consideration.</p>
3.12. List Schedule by login template (tabular and calendar image)	BlazeLIMS includes several tabular reports that provide a listing of samples scheduled, organized in a variety of formats.
3.13. List schedule by test (tabular and calendar image)	BlazeLIMS includes several tabular reports that provide a listing of tests scheduled, organized in a variety of formats.

Feature	BlazeLIMS Capability
3.14. Login from external systems or files	BlazeLIMS sample autologger can log samples and tests as defined in a text, CSV, Excel spreadsheet, or XML file received from an external system, according to a flexible configuration of field formats. These may be created on an ad-hoc basis or be received periodically from other systems in a folder being monitored by BlazeLIMS. This feature is most often used to log samples from ERP or other systems. The BlazeWebServer provides web services to accomplish this as well.
3.15. LIMS resample login	BlazeLIMS provides the capability of creating a new sample (resample) based on an old sample by simply clicking on a button on the log sample screen. The old sample is not automatically cancelled. A link is maintained to the original sample. Alternatively, a resample may be performed for a container within a sample so that resample data is included in the original sample for ease of management.
3.16. LIMS retest login	BlazeLIMS provides a feature for retesting (re-logging) any method and its tests within a sample by simple pushbutton. The user may also reject any method and its tests.
3.17. Event trigger login	BlazeLIMS includes an event trigger system that provides actions on sample and test events. One of the actions is to provide the ability to log in a sample after every nth sample.
3.18. Modify tests assigned to sample during login	BlazeLIMS allows the user to easily modify/add tests assigned to samples during login.
3.19. Ad-hoc login and test assignments	BlazeLIMS allows ad hoc login and test assignments via pick lists or dropdowns.
3.20. Register sample receipt for pre-logged sample	BlazeLIMS includes a receive sample screen to indicate the receipt of samples or containers that were previously logged and allow for entry of conditions and other sample information, printing of labels and worksheets, etc. Sample receipt may be by single sample or batched in various convenient modes (e.g. grouped by testing request, stability draws, collection routes, etc.), often providing visible indication of missing samples or containers.
3.21. Add or delete tests or profiles from logged in sample	BlazeLIMS provides a modify sample screen for adding tests to a logged sample. If enabled, the results entry screen can also allow this function. The system will appropriately change the sample status and/or require re-approval. There is also a cancel sample/test screen for canceling tests in a logged sample. The system will appropriately change the sample status.
3.22. User definable login methods	<p>The user can define templates that which can specify the complete set of login information and actions for a sample. These may be used to populate the log sample screen by simply selecting the template or for use by the autologging functions.</p> <p>The user can define work request templates that can specify the complete set of login information and actions for a set of samples. These may be used to populate the work request by simply selecting the template.</p>

<b>Feature</b>	<b>BlazeLIMS Capability</b>
3.23. User definable login screens	BlazeLIMS allows multiple levels of configuration for the login screens. The user may configure the presence of and names of numerous identification fields in a way that is fully comprehensive of needs and avoids costly customization. Screens are available in various flavors (manufacturing, environmental, clinical, etc.)
3.24. Ease of login	BlazeLIMS insures ease of login primarily by the use of templates which default most values and are easy to select. Field entry is made simple by the use of dropdowns, help tables, special controls and much more. Also, BlazeLIMS has organized the log sample and other screens to make it easy to log samples, split samples, resample, retest, etc.
3.25. Login reports	Receipt and worksheet reports and labels may be created on login or on demand. Email notifications may be sent routinely based on sample type or by exception (e.g. priority, damaged container, etc.) Numerous displays and reports also exist to manage backlog, performance summaries, etc.
<b>4. Labels</b>	
4.1. Print container label (with and without barcodes)	Labels with optional barcodes may be generated on sample logging, receipt or by manual request. Labels may be created for the sample and/or its individual containers or aliquots. BlazeLIMS allows the user to configure labels to print any field associated with the sample/container, including information useful for routing such as testing abbreviations, etc. Labels may also be printed for reagents, standards, instruments, personnel, shipping containers, and much more. Barcodes can also be printed on reports for use as worksheets, etc.
4.2. Print container requirements report from schedule	The sample scheduling system provides a report of container and container preparation requirements for use in sample collection and COC.
4.3. Print labels from logged in samples (with bar codes)	Labels with optional barcodes may be generated on sample logging, receipt or by manual request. Labels may be created for the sample and/or its individual containers or aliquots. BlazeLIMS allows the user to configure labels to print any field associated with the sample/container, including information useful for routing such as testing abbreviations, etc.
4.4. Print shipping labels	BlazeLIMS provides comprehensive tracking of shipments and produces paperwork such as shipping labels, bill of lading, COC. It includes multiple modes of operation in which individual items may be barcoded into a shipment, or all items available for a particular destination, with subsequent validation. This insures optimal management of shipments so as not to miss items.
4.5. Print labels from Schedule	BlazeLIMS will print sample/container labels for a set of samples from the logging schedule. BlazeLIMS allows the user to configure labels with any field associated with the container

<b>Feature</b>	<b>BlazeLIMS Capability</b>
4.6. Print sample receipt	BlazeLIMS provides manual or automatic printing of a sample receipt report when a sample is logged or received based on workflow configuration.
4.7. Print sampling route list from Schedule	BlazeLIMS includes a sample routing function and associated route list report as part of the autolog schedule for multiple sample logging.
4.8. Flask labels (removable)	BlazeLIMS prints labels on demand or automatically when samples are logged or received for the sample, its containers and/or its aliquots (flasks).
4.9. User definable label formats	BlazeLIMS allows the user to define the format and the fields to be displayed on any label to include any database item associated with the sample, work request, shipment, inventory item, etc.
4.10. WHMIS Workplace Labels	BlazeLIMS can print WHMIS hazard labels based on its database of material types/hazards.
4.11. Ease of label functions	BlazeLIMS includes bar coding features in many of its screens to quickly locate samples, inventory items, reagents, work request, shipments, etc. from container labels or from barcodes printed on BlazeLIMS reports.
4.12. Current label printers	BlazeLIMS includes the ability to print labels on most commercial barcode printers.
<b>5. Sample Distribution and Tracking</b>	
5.1. Tracking	The location and processing steps for all samples, containers and aliquots are tracked throughout their life cycle. Tracking may be automatic but also may be enforced via receive and relinquish operations.
5.2. Distribution lists	BlazeLIMS' log sample and/or receive sample functions can produce a distribution list for the samples/containers/aliquots or include such information on labels.
5.3. Chain of custody	BlazeLIMS can produce COC reports for use in collecting samples/containers, and includes its own Chain of Custody tracking of all samples/containers for all laboratory operations.
5.4. Sample routing	BlazeLIMS includes a sample route function for definition of the route order of tests to be performed for a sample. Alternatively, a simple list of the route may be included on worksheets or labels.
5.5. Sample shipping	BlazeLIMS provides comprehensive tracking of shipments and produces paperwork such as shipping labels, bill of lading, COC. It includes multiple modes of operation in which individual items may be barcoded into a shipment, or all items available for a particular destination, with subsequent validation. This insures optimal management of shipments so as not to miss items.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
5.6. Sample storage and retrieval	<p>A simple storage location indicator may be entered into the sample. For more comprehensive storage and retrieval management, the BlazeInventory module allows for tracking and storage of samples in hierarchical storerooms, freezers, box, slot, subslot, etc., including comprehensive tracking of conditions, locations, check in/check out, freeze/thaw cycles, COC, storage rules, disposal, etc.</p> <p>The BlazeLIMS Stability function includes the ability to define storage conditions and locations for its inventory of stored samples.</p>
5.7. Sample storage inventory management	<p>The BlazeInventory module allows for tracking and storage of samples in hierarchical storerooms, freezers, shelf, box, slot subslot, etc., including comprehensive tracking of conditions, locations, check in/check out, freeze/thaw cycles, COC, storage rules, disposal, etc.</p> <p>BlazeInventory provides sample inventory management for stability samples.</p> <p>BlazeInventory has stability reports including the location of samples.</p>
5.8. Sample disposition / disposal management	<p>Sample disposal with special provisions for hazardous materials may be managed in a simple fashion at the sample level with available schedules and reports. Alternatively BlazeInventory manages and tracks the disposal of samples in a more comprehensive fashion.</p>
5.9. On-line access to sample distribution, storage & safety information	<p>BlazeInventory provides storage and safety information and complete item tracking.</p> <p>BlazeLIMS provides a mechanism for capturing/managing versioned SOP and MSDS documents for samples, materials, methods, instruments, etc. A user can view these documents from any BlazeLIMS Client.</p>
<b>6. Assigning Work</b>	<p>In many laboratories, analytical work is implicitly assigned by the arrival of a sample at the input station for an operation. In other situations, tasks may be pre-assigned according to priorities, availabilities, grouping efficiencies, and other factors. In either case, however, many of the same tools described in this section may be used either to assign the work or to monitor progress for backlog, and adjust for bottlenecks, unusual circumstances, etc.</p>
6.1. Grouping Tests By QC Batch Or Run	<p>Tests may be grouped as runs or method based batches for efficiencies all the operations described here including prepping, running analysis, data entry, and approvals, and for the application of QC testing. Collection of tests into uniquely identified batches or runs may be done by barcoding or via comprehensive filters and condition tests. Batches and runs may be processed</p>
6.2. Select and assign tasks	<p>Selecting and assigning tasks may be performed at the testing request, sample or test (aliquot) level according to the accountability distribution within an organization.</p>

Feature	BlazeLIMS Capability
6.2.1. Select tasks by analyst, workgroup, instrument, test, priority, due date	BlazeLIMS provides for assignment of priority to work requests and samples, and the assignment of work requests, samples and/or aliquots to lab groups, personnel, and instruments. A backlog/assignment screen is available at each of these levels and is easily populated with the backlog for various tasks such as receive, prep, analysis, review, approve, etc. Items are ordered by priority and due date, so that the current state and backlog for virtually any operation may displayed, the status of items examined, and work assigned. An interface to Microsoft Project for export/import allows for schedule management, optimization and display by analyst, instrument, priority, etc. for ease of viewing, assigning resources, reporting, including work calendars, etc.
6.2.2. Due date determination	Due dates for work requests, sample and aliquots are calculated based on a combination of turn-around commitments, sequencing of tasks, sample shelf lives before prep and analysis, etc. and can take into account operations with different activity schedules. For example, analyzers can often run 24/7, whereas personnel work 8/5.
6.2.3. Print work list by work group, instrument, test, sample	BlazeLIMS includes work schedule screens and reports by lab group, instrument, person, test, sample, etc.
6.2.4. Work list by test	BlazeLIMS includes a work list feature to view and create work lists by method/test and to print reports of work lists.
6.2.5. Print test backlog	BlazeLIMS includes a method/test backlog report ordered by collections as desired (lab group, analyst, test, due date, priority, instrument, etc).
6.2.6. Print instrument backlog from schedule	A report is available to show instrument backlog from schedules, with color coded indication of expired or soon-to-expire samples.
6.3. Print instrument backlog from active samples	BlazeLIMS includes an instrument backlog report from active samples, with color coded indication of expired or soon-to-expire samples.
6.3.1. Select Analyst Work lists	
6.3.2. Print work group backlog	BlazeLIMS includes a Lab Group backlog report, with color coded indication of expired or soon-to-expire samples.
6.4. Print analyst backlog	BlazeLIMS includes an analyst backlog report.
6.4.1. Specialized Sample group work list	
6.5. Print backlog of expiring samples in time order	The BlazeLIMS Backlog report may be grouped and sorted by due date and priority, with color coded indication of expired or soon-to-expire samples.
6.6. Instrument sequence or control file generation	

Feature	BlazeLIMS Capability
6.6.1. Tray loading list	BlazeLIMS provides for an instrument tray loading list report from QC batches or work lists. It can be sequence oriented or plate layout organized and can include lab QC's as well as unknown samples. It can include printed barcodes for easy scanning into an instrument or can be transmitted directly into many instruments or CDS's.
6.6.2. Transmit sequence file to instrument	BlazeLIMS can produce the tray loading list and transmit directly to the instrument, either via shared folder or using BlazeLink.
6.7. User definable work assignment methods	Work assignment may be done via a round-robin schedule assisted by pre-defined method/personnel relationships. Integration with Microsoft Project allows for inclusion of worker work days and for easy drag and drop assignment methods or load leveling algorithms.
6.8. Analyst Worksheets	
6.8.1. Printed worksheets	BlazeLIMS can automatically print a worksheet during work request or sample logging on receipt or on demand. Worksheets may be on a sample, aliquot, batch or other type of grouping.
6.8.2. Electronic worksheets	BlazeLIMS includes the ability to generate electronic worksheets in Excel in a general form for any aliquot or batch, or using a pre-defined template applicable to a particular method. This provides a powerful mechanism to seamlessly integrate and version control templates in the BlazeLIMS document management system, automatically instantiate and populate them at run time, capture the data in a familiar form and then automatically upload it and archive the worksheet. It preserves legacy investment in these worksheets while providing a fully managed, controlled and integrated function.
6.9. Sample Preparation / ELN	BlazeLIMS provides sample preparation at the sample, aliquot and batch levels, including full-ledged ELN tracking of the process for creating reagents, stock solutions, standards, etc.
6.10. Prep batching	BlazeLIMS supports prep batching, either as a separate batch/operation from analytical batching, or as part of an analytical batch. Prep batches of multiple types may be created (extraction, cleanup, prep, etc.) Features include assistance, enforcement and management of creation and use of reagents and standards, including full vendor/lot traceability, enforcement of multiple expiration rules, comprehensive chemistry calculations, QC statistics, step by step execution with audit trail, worksheets, and more.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
6.11. Reagent management	<p>BlazeInventory supports tracking and management of reagent purchase, creation from other reagents, storage and retrieval, quarantine, testing, usage, expiration using multiple criterion including expiration of ingredients, lot numbers, properties, SOP document management, inventory quantity enforcements with notification, and comprehensive calculations associated with operations performed. . BlazeInventory allows for tracking and storage of samples in hierarchical storerooms, freezers, box, slot, subslot, etc., including comprehensive tracking of conditions, locations, check in/check out, freeze/thaw cycles, COC, storage rules, disposal, safety, etc.</p> <p>In short, a complete ELN capability is provided for managing and use of reagents.</p>
6.12. Standards management	<p>BlazeLIMS / BlazeInventory supports tracking and management of lab standards purchase, creation from other reagents, dilutions, storage and retrieval, usage, expiration, lot numbers, properties, SOP document management, and comprehensive calculations associated with operations performed and QC statistics. In short, a complete ELN capability is provided. The system supports creation and use of blanks, dups, spikes, calibrations, internal standards, surrogates, etc. and their incorporation into batches and aliquots.</p>
6.13. Instrument management	<p>BlazeLIMS supports tracking and management of instruments used in preparations including scales, pipettes, volumetric flasks, etc., monitoring and enforcing proper use and calibration status.</p>
6.14. Personnel management	<p>BlazeLIMS supports tracking of personnel performing various steps of the preparation operation and their qualifications.</p>
6.15. Prep Templating	<p>BlazeLIMS supports creation and use of comprehensive templates defining the prep operations and calculations to provide straightforward execution.</p>
6.16. Produce worksheets	<p>BlazeLIMS produces comprehensive worksheets for the prep process. These can be in the form of printed worksheets using Crystal Reports or live integrated spreadsheets which can be populated and automatically uploaded and captured in the documents management system.</p>
<b>7. Data Capture – Entering Data &amp; Information</b>	
7.1. Manual Keyboard Data Entry	<p>BlazeLIMS provides a wide variety of screens that are fine-tuned for manual entry according to the demands of the workflow. These range from single sample or aliquot to matrix entries of various collections, to spreadsheet entry, to user definable entry methods for repetitive operations.</p>
7.1.1. Single sample by sample (can use bar code for sample id)	<p>BlazeLIMS sample-oriented screens are designed with the Sample Log Number field (positioned first on the screen) capable of receiving a barcode value that automatically locates and displays the desired sample record or any container or aliquot of the sample.</p>

Feature	BlazeLIMS Capability
7.1.2. Single sample by test (bar code sample id)	There are several result entry screens in BlazeLIMS. The Enter Result screen provides single sample, container or aliquot by tests. The screen accepts a barcode.
7.1.3. Multi sample by work list	The Matrix Entry screen is capable of fetching samples based on a wide variety of criterion as a way to enter via a cross tab matrix or via an integrated Excel worksheet. Alternatively multiple samples may be collected in a run or a QC batch and results entered on associated entry screens or related Excel worksheets.
7.1.4. Multi sample by test backlog	The Matrix Entry screen provides selection of samples from a list of backlog aliquots. Alternatively backlog aliquots may be fetched into a QC batch for multiple entry.
7.1.5. Worksheet single sample data entry (spreadsheet)	BlazeLIMS can display/create a data entry worksheet for a single sample using Crystal Reports for paper versions and/or Excel for integrated electronic versions.
7.1.6. Worksheet multiple sample data entry (spreadsheet)	BlazeLIMS can display/create a multi-sample data entry worksheet based on a collection of samples or a QC batch.
7.1.7. User definable result entry methods	Special purpose result entry screens may be configured for repetitive entry of a particular set of data, such as tare and starting weights, ending weights, etc. These provide a high productivity mechanism for entering data from a repeating process.
7.1.8. Spreadsheet or auto-entry limit and status checking	<p>All values entered by any of the methods described above are processed according to the same hierarchy of checking</p> <p>Legality of entry by operator privileges, by status of test/aliquot/sample and by kind of value.</p> <p>Legality of data entry format according to pre-specified data types and formats for integer, fixed decimal, precision, scientific notation, date time, elapsed time, text, text in a dataset, numeric with text overrides, use of symbols such as &lt;, &gt;, etc., capture of files and long text paragraphs, and more.</p> <p>Checking against method based limits such as UDL, LDL, etc.</p> <p>Checking against specs at the product, product-customer, product-quality-code, etc. levels as described below.</p>
7.2. Automated capture via screens	Any of the above screens may be used to automatically capture barcode identifiers and results from instruments whose output is wedged into the keyboard input buffer.
7.3. Automated Instrument Data Entry	Automated data entry from simple devices can input directly to BlazeLIMS screens via a keyboard wedge. Alternatively, BlazeLink provides a flexible, configurable fully automated bi-directional instrument interface.

Feature	BlazeLIMS Capability
7.3.1. RS-232 Instruments	BlazeLink provides a bi-directional serial interface capability. It captures instrument output that it parses to find desired values. The desired values are formatted into an output message that is transferred to the BlazeLIMS Uploader after optional display and approval. It can be configured to handle various bi-directional protocols from simple query sequences to full interchange of sampling and results data (e.g. ASTM 1394-97, proprietary instrument protocols, etc.) BlazeLIMS can provide runsheets that BlazeLink downloads to instruments.
7.3.2. Acquisition Systems (Down / Up Loads)	BlazeLink provides a bi-directional interface capability using downloads/uploads. It captures instrument output that it parses to find desired values. The desired values are formatted into an output message that is transferred to the BlazeLIMS Uploader after optional display and approval. BlazeLIMS can provide runsheets that BlazeLink downloads to instruments.
7.3.3. Instrument Control (Bi-directional)	BlazeLIMS/BlazeLink can be configured for a variety of instrument control protocols, including simple handshaking to elaborate formal protocols (ASTM1394) with exchange substantial information with BlazeLIMS such as patient, tests requested, standards, etc.
7.3.4. Auto sampler control	BlazeLIMS does not include autosampler control, but can provide runsheets, instruments, standards identification, etc.in formats suitable for autosampler use.
7.3.5. Robotic Systems	BlazeLIMS can track robotic operations such as re-arraying or provide commands for such operations.
7.3.6. Review auto entered results	Results can be reviewed via BlazeLink prior to being sent to the LIMS, or reviewed in the LIMS by peers and approved by managers, if desired.
7.3.7. File transfers	BlazeLink performs automatic file transfers via ftp or network shared folders, handling parsing of instrument formatted data, caching and catch up. BlazeLIMS Uploader and Autologger perform file transfers. BlazeLIMS approved results can be exported in files. Files may be details, images, methods, or other raw data files associated with an analyzer run that are automatically transferred to the LIMS and stored in its document management system.
7.3.8. User definable instruments import / export methods	BlazeLink allows the user to define the import and export methods for instruments. A comprehensive and user friendly visual parser may be configured and the parsing debugged using a powerful visual debugger. BlazeLIMS Uploader allows the user to define the map for results uploading.

Feature	BlazeLIMS Capability
7.3.9. List of current instruments and control software	BlazeLIMS and BlazeLink are capable of interfacing to any instrument with the capability of performing analysis output with a file or serial connection in any format (text, CSV, Excel, XML). Configuration to a specific instrument format and protocol does not require custom programming. Example configurations are available for most common analyzers and CDS's, but new instrument can be configured in a very brief session.
7.4. Data Import	
7.4.1. Enter results from samples sent out	BlazeLIMS manages the shipping of samples to outside labs, producing bill of lading and COC paperwork, and then allows for automatic uploading of results that are returned in electronic form. Results may also be entered by the remote lab via the BlazeWeb Client.
7.4.2. Enter results from foreign systems	Entry of results from foreign systems can be performed either by file transfer or by allowing access to the system via the BlazeWeb Client.
7.4.3. Instrument Tracking	BlazeLIMS provides entry or uploading of instrument along with results and associated checking for calibration and maintenance status.
7.4.4. Other Imports	BlazeLIMS provides integration and uploading of other data such as customer masters, instrument masters, specification masters, and more.
<b>8. Specification Checking</b>	Specifications may be defined on the bases of one or more of the following: test type, sample type/test type, sample type/test type/customer, sample type/test type/customer/product grade. All specifications are maintained as versioned records and bound to tests when logged or entered. In this way an intact historical record and the ability to re-process results according to the specification in effect at testing time is maintained. Alternatively, any sample/test may be re-bound to newer specifications if desired.
8.1. One level	BlazeLIMS provides specification checking at a warning level.
8.2. Two levels	BlazeLIMS provides specification checking defined at control spec level.
8.3. Three levels	BlazeLIMS provides specification checking at product spec level. BlazeLIMS also includes domain and method limits and specification limits at the lot release level.
8.4. Missing specifications	BlazeLIMS can detect missing specifications in the production of final reports and COA's.
8.5. Approximate specification checking <, >	BlazeLIMS limits include approximate checking (replacement values) that include <, >, etc. These are carried through and taken into account in the standard equation processing.
8.6. Limit of instrument detection issues	BlazeLIMS includes method definitions for limits of detection and replacement with < or > values or other indicators such as ND. Dilution corrections are also provided.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
8.7. User definable specification checking functions	User definable specification checking may be provided via calculations. Users may also enter override spec violations.
8.8. Ad-hoc specification definition post login	BlazeLIMS allows for the entry of an override specification violation indication.
8.9. Specifications based on test results	BlazeLIMS supports determination of specifications from test results values or history, either on the fly using equations or via periodic statistical analysis and updating
8.10. Warning to user for out of specification (audible, screen message, color, flag)	BlazeLIMS provides a screen indicator and color change as a warning of out of specification results, along with optional modal dialog.
8.11. Custom user defined algorithms for specification checking	User definable specification checking may be provided via calculations.
8.12. Specification Management	Comprehensive tools to manage specification documents with live fields for export/import.
<b>9. Calculations</b>	
9.1. Inter Test	BlazeLIMS provides configuration of equations for performing calculations. Equations can fetch operands from many values within the test, and perform many operations, and many intrinsic mathematical functions.
9.2. Intra Test	BlazeLIMS provides configuration of equations for performing calculations. Equations can fetch operands from many values within the test, values from multiple tests or aliquots, and perform many operations, and many intrinsic mathematical functions.
9.3. Intra Sample	BlazeLIMS provides configuration of equations for performing calculations. Equations can fetch operands from many values within the test, values from multiple tests or aliquots in the sample and perform many operations, and many intrinsic mathematical functions.
9.4. Inter Sample	BlazeLIMS provides configuration of equations for performing calculations. Equations can fetch operands from many values within the test, values from multiple tests or aliquots in the sample, values from multiple samples related via batch, QC relations, or other connections, and perform many operations, and many intrinsic mathematical functions.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
9.5. Descriptive Statistics	BlazeLIMS has several screens for displaying averages and standard deviations of results. It also includes an interface to NWA Quality Analyst NWA Quality Analyst receives exported results and displays statistics in control charts. The control charts include outliers and calculated control limits. BlazeLIMS also calculates QC statistics and statistics for uniformity and dissolution studies. Statistics can be collected, calculated and charted on a broader scale using Hunter for BlazeLIMS.
9.6. Advanced Math Functions	BlazeLIMS equations include advanced math functions such as average, sum, regressions, lot statistics, calibrations and more.
9.7. User Defined Functions	BlazeLIMS includes intrinsic mathematical functions. The site can create additional functions in a plug in module. These functions can then be used in equations by LIMS users in a standard manner via dynamic linking.
9.8. Links to prior results	Special calculation functions provide access to prior results in any equation.
9.9. Trigger/Event Functions	BlazeLIMS includes a trigger system for sample and test events. Events may send e-mail, log samples, and more.
9.10. Library of math subroutines	BlazeLIMS equations include a comprehensive set of intrinsic mathematical functions.
9.11. Sample preparation factors	Complete sample preparation calculations may be configured to provide a comprehensive ELN capability, dealing with mixing chemistry, calculation of properties, and much more. Data can be accessed from associated inventory items, samples, etc. using the BlazeInventory module.
9.12. Linear calibration & method-of-addition calculations	BlazeLIMS provides linear calibration corrections via the QC Batch function from calibration standards, or via manually maintained table lookup Method of addition calculations (mixing chemistry) may be configure in the prep operations.
<b>10. Quality Control Monitoring</b>	
10.1. QC Templates	BlazeLIMS allows the user to define QC templates that may be applied to a QC Batch. In addition, QC may be specified on an ad hoc basis. These templates control the creation and inclusion of QC samples and analytes in the batch such as blanks of multiple types,, dups, spikes, spike dups, calibrations, lab controls of multiple types, negative control of multiple types, check standards, internal standards, surrogates, etc..
10.2. Automatic Generation of Control Charts	BlazeLIMS is interfaced to Northwest Analytical Inc.'s Quality Analyst, which provides control charts via user request.

Feature	BlazeLIMS Capability
10.3. Automatic Statistical Control	BlazeStatisticalControl provides automatic control chart algorithms to be run on data entry, with immediate visual feedback and notification on violations of limits or Westgard or Western Electric rules. Algorithms include Shewart with rules, Cusum, EWMA. Control charts may be configured to run based on process (unknowns) results or instrument/method/qc results so as to control either the customer or lab processes.
10.4. Automatic Trend Analysis	BlazeLIMS provides this capability through the BlazeStatistics module or via automated export to spreadsheets. Trend analysis is also available via the web on an ad-hoc basis using Hunter for BlazeLIMS.
10.5. Automatic Calculation or % Accuracy of Controls	BlazeLIMS includes the automatic calculation of all QC statistics such as % Accuracy, % Recovery, %RSD, %Diff and more.
10.6. Automatic Calculation of % Spikes	BlazeLIMS includes the automatic calculation of all QC statistics such as % Accuracy, % Recovery, %RSD, %Diff and more.
10.7. Automatic Calculation of % Recovered	BlazeLIMS includes the automatic calculation of all QC statistics such as % Accuracy, % Recovery, %RSD, %Diff and more.
10.8. Automatic Calculation of % Difference of Duplicates	BlazeLIMS includes the automatic calculation of all QC statistics such as % Accuracy, % Recovery, %RSD, %Diff and more.
10.9. Internal Audits	BlazeLIMS includes the capability to capture and manage documents associated with internal audits. BlazeLIMS provides QC summary reports for use in audits.
<b>11.Data Analysis and Graphics</b>	
11.1. Data Analysis	BlazeLIMS provides multiple levels of data analysis tools, from easy to use operator level structured screens and reports with filters to a fully ad-hoc web capability suitable for more advanced users using Hunter For BlazeLIMS. Datasets may be viewed graphically and exported to Excel for additional analysis.
11.2. 2D Control charts, trend charts, particle size histograms, and chromatographs.	BlazeLIMS provides control charts via the seamless Northwest Quality Analyst interface, trend charts via a Microsoft Excel Export feature on the Results Summary screen, Charts using Crystal reports or Excel , general charting via the web using Hunter for BlazeLIMS. Histograms are a feature of NWA Quality Analyst charts. Chromatographs and images of spectra can be captured on the Enter Results screen and viewed or included in reports.
11.3. 3D	BlazeLIMS uses Microsoft Excel which provide tabular and graphical chart (line, 2D, 3D, etc.) displays of the data. BlazeLIMS' Crystal Reports can produce reports with simple graphics (2D, 3D). Hunter for BlazeLIMS provides a wide variety of 3D charts.
<b>12.Data Edit / Correction</b>	

<b>Feature</b>	<b>BlazeLIMS Capability</b>
12.1. Edit sample information	BlazeLIMS includes a Modify Sample screen that provides the ability to modify appropriate sample information with an audit trail, forced comments, etc. Every table contains a version number that is incremented when changes occur. It does not allow changing system generated time stamps and audit trails.
12.2. Edit Test Results	BlazeLIMS includes the ability to modify test results with an audit trail, forced comments, etc. Every table contains a version number that is incremented when changes occur. A user can see that a table has been changed by the fact that the version number is greater than one.
12.3. Audit trail changes (keep original data plus info on changes)	BlazeLIMS maintains a full audit trail on every sample and test related table. Every change is audited.
12.4. Force comments for all changes	BlazeLIMS provides an option for Forced Comments for changes. BlazeLIMS includes a dropdown list of change reasons that can be used in Forced Comments. You must enter a comment for each change. There are sample wide or test oriented Forced Comments. The site can define the events for which Forced Comments are demanded.
12.5. Change Actions	Reports, certificates, calculations, and email will reoccur if the actions of the user cause the event to reoccur. For example, changing a result of a calculation will cause the calculation to be recalculated.
12.6. Ease of changes	BlazeLIMS allows the user to just make changes to a sample and appropriate events will occur.
12.7. Automatic Data Transfer Changes.	Data can be re-sent from an instrument and the system will update all of the results appropriately if allowed. The re-sent data could include a different comment in the reference field.
<b>13. Checking, Reviewing and Approving Results</b>	
13.1. Check / Verify Tests	BlazeLIMS includes the ability to check test results, usually employed to check data entry operations.
13.2. Review / Verify Tests	BlazeLIMS includes the ability to review test results, usually employed as the lab approval.
13.3. Approve / Verify Tests	BlazeLIMS includes the ability to approve test results, usually employed as the QA approval. Customers will only have access to approved results.
13.4. Reschedule a test	A method and its tests may be re-logged for a rerun with a single pushbutton. The original run can be rejected with a single pushbutton.
13.5. Reschedule a sample	A sample may be easily re-logged for a resample.
13.6. Approve Samples	BlazeLIMS includes manual and automatic approval of samples, optionally including all the tests as well. In addition, BlazeLIMS includes the ability to do automatic approval of results in spec.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
13.7. Communicate status to external systems	BlazeLIMS has a Publish feature to automatically export results and status to an external system on a test-by-test basis or sample basis.
13.8. User definable review and approval methods	The user may define review and approval workflow on a sample type basis.
13.9. Approval Notification	BlazeLIMS provides the capability of notifying via email when a sample is finished and ready to be approved. This may be easily pre-configured to apply to various roles.
<b>14.Reporting Results</b>	<p>BlazeLIMS provides a superior reporting capability for all reports, using industry standard reporting tools (Crystal Reports, Excel, Word) that are highly integrated to so as to provide a configurable, extensible and easy to use mechanism, avoiding custom programming and yet providing any report using the best tool for the job. Reports can be configured to run on menu selections, pushbuttons, events, and time scheduled. Reports are managed and stored on the server and downloaded as needed to the clients. Issues such as database connectivity, report context (sample, testing request, batch, etc.) are automatically handled by BlazeLIMS.</p> <p>The BlazeLIMS integration with Excel in particular provides an extremely cost effective mechanism for incorporating legacy workbooks as fully automated reports in the LIMS. For example, elaborate DMR's, final reports with fixed layouts containing charts and images, etc. can be quickly and easily integrated and centrally managed, preserving the often substantial investment in layout, end user satisfaction, etc. This insures that the lab can continue to support the reports with the familiar and powerful end user tool that Excel has become.</p>
14.1. Single Sample Reports	BlazeLIMS includes many single sample reports using Crystal Reports, Excel or Word. These may be easily customized to suit a particular need.
14.2. Group Analysis Reports	Analyses may be grouped by Work Request, QC Batches or ad-hoc collections based on a wide variety of criterion or simple barcoded in.
14.2.1. Multi sample reports	BlazeLIMS includes Work Request, run list and QC Batch reports. This includes results from multiple samples, in addition to reports such as backlog by group, instrument, analyst, and many more.
14.2.2. Summary reports	BlazeLIMS includes numerous summary reports via crystal reports and Hunter for BlazeLIMS.
14.3. Report previews	BlazeLIMS' reports are by default setup to be displayed in a preview mode. Automatically printed reports from the reports scheduler are printed, mailed or published to a folder.

Feature	BlazeLIMS Capability
14.4. Certificate of Analysis Reports	BlazeLIMS reports are all easily customizable by the site. BlazeLIMS provides special features for COA reports including the ability to define different COA formats for different products and customers. BlazeLIMS, utilizing Crystal Reports, can create simple cross tab reports. BlazeLIMS encapsulates the report process (in order to do previews, email, etc.) and provides the ability to generate a report to a document. This provides a flexible and powerful environment to meet any COA need, no matter how specialized or elaborate. Issued COA's are also captured in the document management system.
14.5. Graphical Results Reports	BlazeLIMS, utilizing Crystal Reports, supports Graphical Results in reports. Hunter for BlazeLIMS also provides graphical reports.
14.6. Chain of custody report	BlazeLIMS includes a Chain of Custody report.
14.7. Link to E-Mail Report Distribution	BlazeLIMS includes email report distribution that is fully configurable on a report-by-report basis.
14.8. Ability to Fax	BlazeLIMS includes fax report distribution that is fully configurable on a report-by-report basis.
14.9. User definable reports	The user can define their own Crystal Reports and easily include them in the BlazeLIMS Client menus, tie them to specific customers or products, and automatically schedule them at periodic intervals.
14.10. Ad-hoc Reports	Hunter for BlazeLIMS provides for a wide range of Ad-hoc reports. In addition, BlazeLIMS provides the ability for the user to define filters on any field of any screen and print a report. Crystal Reports includes a Crystal Query tool that provides the user with the ability to perform ad hoc queries against the database and print a report.
14.11. Report tools (standard or proprietary)	BlazeLIMS utilizes Crystal Reports Professional, Excel and Word as the built-in reporting tools. Hunter for BlazeLIMS may be used for web based reporting.
14.12. Export data sets (small and large) to external systems	BlazeLIMS includes the ability to export data to external systems on demand, periodically or at specific events. Exports can be based on individual values, as required to send data to a SCADA or control system (OPC, InfoPlus, and others), or large data sets as in the case of final approval of a project or study, monthly billing, monthly DMR reports, etc. Interfaces are available for SAP/QM or SAP/Batch and other ERP, invoicing, etc systems.
14.13. Audit trail reports	Audit trail data is maintained in a separate table accessible to the report writer. Audit trail data can be readily added reports as needed (samples, test, etc.). An audit trail summary report is available.
14.14. Comment reports	Multiple comments are available for every prime table in the system and are accessible to the report writers. They are included in a number of reports that are provided, and can be easily added to others.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
14.15. Control Chart Reports	Control Charts are created within NWA Quality Analyst, which provides its own reporting capability. They can also be created in Excel and are available in the Hunter for BlazeLIMS product.
14.16. Reports to files (disks)	BlazeLIMS provides the ability to deposit any report in a file folder for access by other systems. You may also create an ad hoc export of data from any screen into a Microsoft Excel spreadsheet.
14.17. Control of Automatic Printing	BlazeLIMS may be configured to control the automatic printing of a report on various events such as sample logging, ready for approval, approved, etc. Reports may also be configured to run automatically according to a defined schedule.
14.18. Contract Laboratory Program Reports & Diskette	BlazeLIMS contains many management reports that are used by contract laboratories.
14.19. Ad Hoc Query	BlazeLIMS provides multiple levels of ad hoc query capability tailored to fit the needs of particular users. Screens are provided to find a set of work requests, samples or results using entry of a large set of possible filters. Data can be exported to spreadsheets. Hunter Lite provides a similar structured but more comprehensive web based query, and Hunter provides a fully ad-hoc query capability for the power user. In addition, filters can be set on any screen to define the dataset available for display and export to excel.
<b>15.Managing Lab Operations</b>	
15.1. Sample status reports	BlazeLIMS includes sample status reports such as backlog, overdue, and unapproved reports. BlazeLIMS provides a List Sample screen that displays all samples and their status. This screen can be printed.
15.2. Workload reports	BlazeLIMS includes Pivot (Microsoft Excel) reports that provide this type of management information.
15.3. Overdue reports	BlazeLIMS includes an overdue report that is based on a sample exceeding the due date. BlazeLIMS includes a backlog report based on a sample with a status of logged.
15.4. Instrument loading reports	
15.4.1. Tests performed on instruments by operator	BlazeLIMS includes comprehensive reports on instrument usage by instrument, operator, method, and more.
15.4.2. Tests by instrument for instrument utilization and PM	BlazeLIMS includes reports on instrument usage, utilization, and PM schedules.
15.5. Instrument calibration management	BlazeLIMS includes a complete instrument inventory with defined calibration, validation and pm schedules. Reports are available for calibration history, schedules, etc. Warning notification may be sent when expirations approach and the use of unsatisfactory instrument in analyses or prep prevented.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
15.6. Personnel loading reports	BlazeLIMS includes reports of the history of tasks performed by personnel.
15.7. Accounting reports	
15.7.1. Cost allocation report: total costs allocated by account	BlazeLIMS allows the site to define an average test time and costs for tests and methods. A report is available which summarizes costs on an area or project basis.
15.7.2. Proforma invoices	BlazeLIMS includes a proforma invoice and quotation reports.
15.7.3. Cumulative charges per account	BlazeLIMS allows the site to define an average test time and costs for tests and methods. A report is available which summarizes costs on an area or project basis for a selected time interval. A timecard capability allows personnel to record time spent on various projects, customers, etc. and the associated charges may be included in charge reports.
15.8. Quality Assurance reports	BlazeLIMS provides QA summary reports on a batch, instrument and lab basis.
15.9. Capability Catalog	BlazeLIMS provides Test Type and Method configuration reports. These reports provide a list of analyses the lab is capable of performing in-house along with detection limits, etc.
15.10. Transaction Log listing and maintenance	BlazeLIMS provides a transaction log and associated reports for use in investigating response times and activity levels.
15.11. Inventory management	<p>The BlazeLIMS Inventory module provides comprehensive management of inventory for any stored item, from expendables, to reagents, to samples, including complete life cycle and inventory quantity management, warnings for expiration or low or high quantities, support for ELN functionality as integrated with reagent, standards, and sample prep, etc. Expiration is calculated from manufacturing expiration, shelf life, open shelf life, freeze/thaw cycles, temperature excursions and/or shelf life of component reagents. Suppliers of materials are managed as well.</p> <p>BlazeLIMS includes inventory management of stability samples.</p>
15.12. Instrument Calibration Reports	BlazeLIMS' Instrument Calibration function includes history records for previous calibration, validation and pm events.
15.13. New Instrument Reports (benchmarks)	BlazeLIMS provides reports of instrument validation results.
15.14. Late Calibrations	BlazeLIMS provides reports and warnings on late calibrations.
15.15. Exception Reports	BlazeLIMS provides a number of exception reports for various events in the system such as off spec results, QC violations, late calibrations, etc.
15.16. Reagent & standards inventory reports.	The BlazeLIMS Inventory module provides a comprehensive set of reports for reagents and standards, summarizing by data such as expiration, usage levels, check out status and more.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
15.17. Training	
15.17.1. Training records	BlazeLIMS provides a set of training tables that manage the training records of BlazeLIMS users.
15.17.2. Training reports	BlazeLIMS includes a training report showing the tests/methods or other activity for which a BlazeLIMS user has had trained, including expiration dates, etc.
15.17.3. Training reminders	BlazeLIMS provides training reminders.
15.17.4. Training worklist	BlazeLIMS provides a training worklist report.
15.18. Approved supplier list	The BlazeLIMS Inventory module provides a table of approved suppliers with ties to the items they supply, part numbers, costs, etc.
15.19. Automatic Event Scheduling	BlazeLIMS incorporates a comprehensive scheduling capability to facilitate laboratory operation. It supports interval (once a day, week, month, etc.), calendar (absolute dates), stability sampling (according to stability schedule frequencies), and clinical trial (according to patient visits) sampling schedules for sampling and sample logging, instrument calibration and maintenance, report generation, and more as referenced throughout this document. Schedules are flexible as to intervals (hour, day, week, month, year) and propagate themselves into the future as specified to avoid tedious maintenance.
15.20. Environmental Monitoring	BlazeLIMS has a fully configurable set of features to support comprehensive environmental monitoring, including management and scheduling of collections with COC, analysis, alarms and alerts, messaging, and targeted performance reporting.
<b>16.Document Management</b>	
16.1. Capture, Store, View and Edit Documents	BlazeLIMS provides document management to capture and store documents of any type and view and edit them where utilities are available on the client to do so. Documents are automatically moved to the server, versioned and stored in a catalog of protected folders or as blobs in the database, and then served back to the client for viewing or editing. Documents may also be catalogued by references to other document management systems via shared folder or URL.
16.2. Document Storage Context	BlazeLIMS documents are managed in the context of configurable types, including but not limited to testing requests, samples, aliquots, results, instruments, materials, sample types, methods, projects, etc.
16.3. Managed Documents	Document types may be configured to be managed, in which case new or edited documents must proceed through a review and approval process before being available for use.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
16.4.      Linked Documents	Certain document types are linked according to historical usage. For example, executing a method will link to the active version of the method SOP so that the specific version used may be displayed at a later time.
<b>17. Alarms and Alerts</b>	
17.1.      Alarm and alert infrastructure	BlazeLIMS provides a standard infrastructure for alarms and alerts associated with abnormal events and conditions. Many of these are itemized in the appropriate section of this document , and include events associated with lifecycle workflow processing of work requests samples, containers and aliquots, including QC and specification related events, instrument calibration and maintenance, inventory workflow lifecycle events and quantity limits, training schedules, etc.
17.1.      Alert Configuration	Alerts of all types are fully configurable at the appropriate level, with the ability to combine customer, client, sample type, work request type, item type, instrument type, etc. in driving the initiation of an alert.
17.2.      Notifications	Notifications include immediate visual feedback, e-mails, and publication in a dedicated messaging alert system, including the ability to customie message content by configuration.
<b>18. CAPA</b>	
18.1.      Create, and Manage Quality Events	BlazeLIMS provides for the creation and management of quality events through its CAPA system to support continuous improvement. Events are created and then tracked through a process of investigation and action. Quality events are categorized by configurable types, and linked to the entities of interest such as customer, sample, aliquot, testing request, material, instrument, etc.
18.2.      Template Corrective and Preventive Actions	BlazeLIMS quality event templates may be defined based on configurable event type to add structure to actions to be taken, including investigation and actions steps, along with linkage to the responsible user by name or by role assignments. These may be modified on an ad-hoc basis and an investigation proceeds.
18.3.      Automatic Creation of Quality Events	BlazeLIMS CAPA may be configured to automatically create a quality event on specified LIMS events, such as receipt of a damaged sample, or encountering of an OOS result.
<b>19. ELN</b>	

<b>Feature</b>	<b>BlazeLIMS Capability</b>
19.1. QC ELN	BlazeLIMS provides a comprehensive and configurable ELN functionality for method execution, including configurable calculations, capturing and validating instruments, reagents and standards used, managing and enforcing expirations, lot tracking, automatic concentration calculations across related material, step by step instructions and notes and much more. These functions are available at multiple levels, including reagent and standards preparation, sample, aliquot and batch execution, and even for managing manufacturing batches. All operations are linked to associated entities to provide full backwards and forwards traceability for resources used.
19.2. QC ELN Integration	BlazeLIMS QC ELN functionality is fully integrated with all associated resources as managed by other LIMS function, including reagents and standards, instruments, personnel, samples, aliquots, batches, CAPA and more, providing a seamless system that is easy to use and comprehensive.
19.3. R&D ELN	BlazeLIMS provides a comprehensive R&D ELN via a strategic partnership and integration with Kinematik's eNovator, based on the OpenText platform. eNovator provides flexible and powerful organization and management of the R&D function at multiple levels of the organization, giving the R&D engineer superior tools to capture, organize, execute and document R&D activities. In addition eNovator is integrated with BlazeLIMS or any instrument to provide convenient and error free management of testing request and results receipt and cataloging.
<b>20.Customer Management</b>	
20.1. Customer Master	BlazeLIMS maintains a customer master with optional customer sites. Customer demographics may be managed within BlazeLIMS or automatically imported from enterprise applications which act as masters (SAP, etc.).
20.2. Integration with LIMS/LIS functions	Projects, studies, work requests, samples, inventory items, CAPA quality events, specs, testing templates, and more can be linked with customer and site and a customer centric view provided for ultra-responsive support.
20.3. Results and Notifications	Notifications and results may be automatically sent to customers via e-mail, fax, export to folders or via the BlazeLIMS web portal.
<b>21.Case Management</b>	
21.1. Patient Centric	BlazeLIMS provides for the management of patient information including patient id, demographics, patient history.
21.2. Integration with LIMS/LIS functions	BlazeLIMS integrates patients with clinical trial management and tracking, clinical testing, patient history analysis and tracking.
21.3. HIPAA Support	BlazeLIMS provides features to enforce management of HIPAA privacy issues for data security.

Feature	BlazeLIMS Capability
<b>22.System Maintenance</b>	
22.1. System Data maintenance	BlazeLIMS data is stored in a relational database such as Oracle or Microsoft SQLServer. Database backup may be provided by the database vendor or third party tools. Blaze Systems can assist in setting up schedules for automated backup and other DBA tasks such as index and statistics rebuilding.
22.2. Archiving Result Data Process data	The Blaze Archive module provides a mechanism for archiving data from the production database to an archive database as needed by the site and according to configurable criterion. BlazeLIMS and SQLServer/Oracle database technology can readily store decades of data for even the largest laboratories without impacting performance.
22.3. Result Export Data	The BlazeLIMS Client includes the ability to export data into Microsoft Excel from any screen. BlazeLIMS reports using Crystal Reports can export data into a variety of other systems. A configurable capability provides export of single values to process control systems.
<b>23.Information Access – On-line</b>	
23.1. SOPs	BlazeLIMS includes the ability to capture and manage versioned SOP documents with approval and activations steps. Current SOP's may be viewed via pushbutton from the operational screens. SOP's may be handled for tests, instrument, sample types, inventory, and much more.
23.2. Method development	BlazeLIMS includes the ability to define Methods and track and adjust detection levels, etc. as well as DOC runs.
23.3. Method validation	BlazeLIMS includes the ability to define Method validation limits.
23.4. Supporting technical information	BlazeLIMS includes the ability to capture and manage documents of all types and tie them to the proper database records. This includes instruments, methods, sample types, materials, samples, work requests and more.
23.5. Historical QA Data	BlazeLIMS maintains all QA data online for reporting and summarizing.
<b>24.Database Structure</b>	
24.1. Flat File	BlazeLIMS utilizes standard relational database technology for permanent storage. BlazeLIMS exports and imports data in flat file form for a variety of functions.
24.2. Relational	BlazeLIMS utilizes standard relational database technology for permanent storage. Oracle and SQL Server are supported.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
24.3. Client Server / Distributed database	BlazeLIMS is a three tiered (thin client) client/server system and can support a variety of multiple database configurations. This insures no lock ups, maximum scalability, superior response time, assured backups, reliable operation of non-interactive tasks, low IT maintenance, trouble free operation on LAN and WAN (using TCP/IP) and much more.
24.4. Match to current information structure / relationships	The BlazeLIMS data model is one of the major strengths of BlazeLIMS. It has been designed and built using industry standard data analysis and design methodologies and provides a superior match to real world laboratory information structures. In addition these structures appear on the screen in a logical and friendly organization, mapping well to user mental models. Primary names may be configured to match user terminology and workflow configured to user needs. The combination of these settings enables the site to tailor the operation of the LIMS to closely fit their desired laboratory information and workflow.
24.5. Match to current laboratory material/test/specification structure	The superior BlazeLIMS data model with its mapping to real world structures, along with configurability of all names, matches lab material/test/specification needs in an outstanding fashion. The BlazeLIMS data model is available to potential customers for appraisal of the fit to the laboratory.
24.6. LIMS sample / result data base structure: Assess fit to laboratory	The superior BlazeLIMS data model with its mapping to real world structures, along with configurability of all names, matches lab information needs for samples/aliquots/results in an outstanding fashion. The BlazeLIMS data model is available to potential customers for appraisal of the fit to the laboratory.
<b>25.Data Integrity</b>	
25.1. Transactional integrity	All BlazeLIMS operations on the database are transaction bounded and designed and built to insure integrity. Operations that might destroy integrity are prohibited. Data integrity problems do not occur in BlazeLIMS because of our outstanding design and implementation of the transaction environment.
25.2. Data integrity report	BlazeLIMS does not include a data integrity report. However, reports can be generated from Oracle or SQLServer.
25.3. Data recovery after fault	BlazeLIMS automatically performs a rollback on faults. Other types of recovery are maintained by the database system software and have worked very well.
25.4. Data integrity during concurrent development	Blaze Systems insures application data integrity during concurrent development via a set of utilities and procedures that properly introduce new versions into the production environment, combined with use of a separate development/test environment where justified.

Feature	BlazeLIMS Capability
<b>26.Program Structure</b>	<p>BlazeLIMS provides a 3-tier client server architecture which insures robust, scalable, maintenance free operation. The program design is highly modular, and object oriented, taking full advantage of the powerful encapsulation, strong data typing, polymorphism and inheritance capabilities of C++ and C#, which are far superior to late binding languages such as VB. As such it is readily extensible with minimal impact on existing functions. In addition, it is segmented into functional modules at the implementation level (LIMS, inventory, stability, instrument interfacing, maintenance management, web portal, etc.). In addition, it provides powerful and effective linkages to external user tools such as Crystal Reports, Excel, Word, Northwest Analyst, and more, insuring the available of the best of both worlds.</p>
<b>27.LIMS Performance</b>	<p>BlazeLIMS provides a 3-tier client server architecture, an optimized and effective physical schema, and a development toolset that insures highly structured database queries so that performance is extremely scaleable and reproducible. BlazeLIMS also provides performance-monitoring tools and reports to assist in managing large, distributed enterprise installations. As a result, we rarely receive support calls on performance issues, even for very large and widely distributed installations.</p> <p>BlazeLIMS is designed specifically to avoid concurrency control problems by keeping transactions windows short and designing locking strategies to be robust.</p> <p>Performance is a complex function of many variables such as server and client hardware, network topology and equipment, workload mix, etc., so meaningful benchmark data is difficult to develop. Our users have documented average transaction times in the 1-2 second range for large systems.</p>
<b>28.Database Tools</b>	
28.1. User definable tables.	<p>BlazeLIMS is built using a superior CASE tool, the BlazeBuilder. It maintains all database, screen, report, menu, security, etc. information at the meta level. As a result, the addition of custom tables and associated support is largely automated and very cost effective. Nevertheless, this is rarely needed, as the COTS features and configurability of BlazeLIMS provide the flexibility and extensibility to meet user needs for all laboratory functions. The Blaze Builder may be used to add user-defined tables to the LIMS for extending the LIMS if justified.</p>
28.2. User definable fields	<p>BlazeLIMS provides a comprehensive set of user configurable general purpose fields that make the addition of user fields virtually unnecessary and eliminate the need for costly customization. Also see 21.1 above.</p>
28.3. User definable indexes	<p>The Blaze Builder may be used to add user-defined indexes to the LIMS, or they may simply be added to the database. The need to do this is extremely rare, as the system is pre-configured with the indexes required to provide excellent performance.</p>

<b>Feature</b>	<b>BlazeLIMS Capability</b>
28.4. User definable field expressions	BlazeLIMS provides a comprehensive set of user configurable field expressions that eliminate the need for costly customization. Also see 21.1 above.
28.5. User definable field authorities by data type, category, group, user	BlazeLIMS provides seven categories of user access, with fine-grained tuning within each category, which define field and function authorities. A user may be assigned to one or more of these categories. The Blaze Builder may be used to modify the system further if needed.
28.6. Import / Export LIMS modules (login/result entry methods, screens formats, reports)	BlazeLIMS provides superior import/export function to manage system configuration bulk loads, migration, etc. These functions manage all the complexities of achieving relational integrity with new or existing records when loading sets of related data.
28.7. Automatic restructure of old data into new structure	<p>BlazeLIMS provides automated restructuring of the database as need to support upgrades to new releases while maintaining full integrity of the data.</p> <p>Blaze Systems is capable of migrating data from legacy systems of any brand into the BlazeLIMS database and has developed a set of tools that makes this more efficient. This reduces the effort to the work required to clean up legacy data that often lacks consistency and integrity.</p>
<b>29.Configuration Tools</b> (configuration of LIMS to meet work flow requirements)	BlazeLIMS may be configured via flexible and easy-to-user screens or by bulk loading from spreadsheet input, or both. Taken together they provide a high effective and efficient mechanism for configuring BlazeLIMS.
29.1. Material definitions	The Sample Type table is used to define products and materials and the workflow associated with their processing. In addition, material types may be defined with properties, safety, MSDS, etc. and referenced in the Sample Type.
29.2. Test definitions	One of the strengths of BlazeLIMS as compared to many other LIMS is the structure and flexibility of its test definitions, which allows for minimum redundancy while still providing configurability of multiple testing cases and strategies. The Test Type table is used to define individual result properties. The Method table is used to define tests including all properties such as results (Test Types), instruments, lab groups, cost, time to run, QC templates, SOP's and much more.
29.2.1. Tests tied to specific materials	The Sample Types and or Log Templates are used to define default tests for specific materials. Together they provide a powerful way to configure multiple ways in which tests may be applied.
29.2.2. Standard tests	The Sample Types and /or Log Templates are used to define standard tests.
29.2.3. Ad-hoc test definition during login	The Log Sample screens permit ad hoc test definition during logging.
29.2.4. Pass/Fail tests	BlazeLIMS allows the definition of Test Types with text values such as Pass/Fail.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
29.2.5. Free Comment tests	All tests include the ability to enter free comments and/or to capture documents which can be used either as the final result or to augment the final result.
29.2.6. Menu choice tests	Test Types defined with legal text values are presented to the user for selection via a drop-down menu.
29.2.7. Numeric tests	Test Types can be defined as numeric tests with associated optional format rules.
29.2.8. Numeric with calculations	Test Types can be defined as calculated tests with attached equations.
29.3. Result/Observation definition	Test Types can be defined as observed tests.
29.4. Algorithm definition	Algorithms are defined as equations with Excel like symbolic entry and a powerful reach to fetch related data from many different tables.
29.5. Tools for building algorithms	Equations are entered symbolically and are thus very easy to create. BlazeLIMS validates the equation syntax for proper format, legal operands, etc.
29.6. Profile definition	BlazeLIMS allows the definitions of Log Templates, which are profiles for logging samples.
29.7. Time Study definition	Test definitions include duration and other time based information that allow comprehensive scheduling and time study.
29.8. Specification definition	BlazeLIMS allows the site to define a specification as a limit with up to 4 levels (warning, control, specification, lot release) with up to 4 levels of access fields (sample type, test type, product code, customer). Each level also includes specification definition. Work requests may also have specification definitions in their templates. All specifications are maintained as versioned records and bound to tests when logged or entered. In this way an intact historical record and the ability to re-process results according to the specification in effect at testing time is maintained. Alternatively, any sample/test may be re-bound to newer specifications if desired.
29.9. Revision Control	BlazeLIMS tables include a revision control field that is incremented each time a change is made to the table. Revision access to tables is granted to users on a fine-grained basis.
29.10. Audit Trail changes	BlazeLIMS includes an Audit Trail table that captures changes made to any table along with time, user, and old and new values.
29.11. Configuration Reports	BlazeLIMS includes Crystal Reports configuration reports for each Configuration table.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
29.12. Time required to add one LIMS material with one test and specification	The Sample Type, Method, Test Type, and Limit tables each contain many optional fields. However, the tables can each be defined by simply entering a name, description, and format. For example, Sample Type requires a name and a reference to a method.. Method requires a name and a reference to a test type. Test Type requires a name. Limits typically require a Sample Type name, Test Type name, and limit value(s). A person knowing these values could add the information within a 1 minute and be ready to log a sample. Bulk loading may be performed from a spreadsheet.
29.13. Time required to add on material with 10 tests and specifications	The Sample Type table contains a tabbed section for entering default tests. Conveniently, BlazeLIMS allows the user entering Test Type names to make entries by simply entering the first several unique characters of each Test Type name. Therefore, ten tests and a specification could easily be entered in a 2-3 minute time frame.
29.14. Time required to interface instruments to LIMS	Blaze Systems typically estimates one half day as the effort required to interface an instrument type (a type is an output format) to BlazeLIMS. Since the Uploader and BlazeLink functions require only point and click operations to configure an interface to an instrument, Most of the time is typically spent configuring the instrument to output the needed report(s).
29.15. Correct association of specification with historical records after a change in specification	BlazeLIMS automatically associates a test record with a specific version of a Limit. A user can bind a sample to a newer limit if desired.
29.16. Correct association of information with historical records after a change in reference information	Limits, domains and equations are maintained as versioned tables and bound to testing at logging or analysis time so that changes to reference information d not impact the historical records. Many fields are captured in the sample/test in order that they might be adjusted at run time and a proper historical record maintained.
29.17. Multi-lingual	Selected operational screens may be configured for multiple languages.
<b>30.Numerical Representation</b>	
30.1. Internal representation of numeric values	Result values may be numeric, text or an attached paragraph or document.
30.1.1. Number of digits	BlazeLIMS stores 15 digits for the primary results value.
30.1.2. Picture statements	Picture statements may be configured for any test at the test type or method/test type level, to include number of decimals, significant digits, alphanumeric format, etc.
30.2. Rounding issues	BlazeLIMS supports two rounding rules, Odd-Even or Five and Greater for numeric fields where rounding is an issue. In addition, for many numeric fields where rounding is not an issue but precision can be, BlazeLIMS uses the G format so that a wide dynamic range of values is possible.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
30.2.1. User definable rounding rules	BlazeLIMS may be configured to use the odd-even method as specified in ASTM E29 or five and greater. For results values BlazeLIMS also maintains the raw result entered and calculated a separately rounded results for COA's as driven by customer specifications. These are also useful for equations where un-rounded data is preferred as inputs.
30.2.2. Odd – Even	BlazeLIMS can be configured to use the odd-even method as specified in ASTM E29 for processing entered results and other values.
30.2.3. Five and greater	BlazeLIMS can be configured to use the five and greater method for processing entered results and other values.
30.3. Comparison Operators (<, >, +, -)	BlazeLIMS allows the entry of data with comparison operators and optionally substitutes comparison operators when detection limits are exceeded. These are also carried through equations to produce a result with a comparison operator if it can be determined.
30.4. Data Types	BlazeLIMS supports a comprehensive set of data types for result values.
30.4.1. Text	Result values can be defined as text and a legal set of text values defined. Mixed mode (numeric/text) may be defined for indicators such as ND and TNTC.
30.4.2. Essay/memo	Result values can be defined as a paragraph of text or a file (Word, Image, etc.), which may be captured.
30.4.3. Integer	Result values can be defined as numeric integer
30.4.4. Floating Point	Result values can be defined as numeric floating point.
30.4.5. Fixed Point	Result values can be defined as numeric fixed point.
30.4.6. Scientific notation	Result values can be defined as scientific notation.
30.4.7. Significant digits	Result values can be defined as significant digits to properly cover results with a precision but a wide dynamic range.
30.5. Logical	Result values can be defined as legal text with good and bad indicators.
30.6. Date	Result values can be defined as date/time.
<b>31.String Manipulation Functions</b>	The equation processor supports both numeric and string operations (comparison, concatenation, etc.) and a wide variety of embedded functions for string manipulation.
<b>32.Audit Trails</b>	An audit trail is maintained for edits to all tables in BlazeLIMS and is available for easy viewing.
32.1. Result level edits	BlazeLIMS audits result level edits. All audits include the field modified, user name, revision, date, old value, and new value.
32.2. Sample level edits	BlazeLIMS audits sample level edits. All audits include the field modified, user name, revision, date, old value, and new value.
32.3. LIMS database structure edits	An audit trail is maintained for all edits to database structures.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
32.4. Test Structures	Test structures are initially defined in the BlazeLIMS builder, which includes the ability to include comments.
32.5. Specifications	The BlazeLIMS Limits table includes the ability to enter a description and comments for the Limit. The Limits table is managed with record auditing, which presents an Audit History table to the user and allows the user to display all previous revisions of the Limit.
32.6. LIMS methods	BlazeLIMS audits all changes to the Method table. In addition, BlazeLIMS contains a simple document management capability that includes the capture and management of SOPs, Word documents on Work Requests, any type of document on test results, and an audit trail describing revisions.
<b>33.Change Control</b>	
33.1. Code Change	The source code is maintained in a source control system utilizing associated procedures. This system is managed per IEEE-828 configuration control standards.
33.2. Static Table and specification	Access to change static tables and specifications is controlled for each LIMS user and changes are fully audited.
33.3. LIMS methods (login, result entry...)	Access to change LIMS methods, sample types, etc. is controlled for each LIMS user and changes are fully audited.
33.4. LIMS Reports	The BlazeLIMS reports that are changed by the customer are stored in a separate folder from the standard release and change control may be done using Source Safe if the user desires.
33.5. Security	Security over all LIMS tables and operations is controlled on a user or user group basis with complete audit trail and flexibility of configuration.
<b>34.Hardware</b>	Blaze Systems publishes a list of recommended minimum hardware configurations for running BlazeLIMS clients and servers. It is available on request, but in general requires a Windows Server and Windows desktop or mobile client platforms. BlazeLIMS is available as a hosted system as well.
<b>35.Warranty</b>	
35.1.1. Hardware components	Computer hardware vendor warranties vary. Please consult your computer hardware vendor.
35.1.2. Software	BlazeLIMS includes 45 days software warranty. Additional software support is available on an annual basis. The first year of support is included in the license fees.

Feature	BlazeLIMS Capability
<b>36. User Friendly Interface</b>	
36.1. User Friendly Characteristics	<p>The BlazeLIMS user interface provides the following user friendly characteristics:</p> <ul style="list-style-type: none"> <li>• Standard Windows MFC look and feel</li> <li>• Panels for fast shortcuts to screens, reports, folders, etc.</li> <li>• Enforced consistency between screens in user friendly naming, layout, visible clues, context sensitive help.</li> <li>• Visible functionality</li> <li>• Expected results, no surprises</li> <li>• Immediate, visible, superior feedback, including user level messages with useful parameters</li> <li>• Enforced visible formatting/constraints and lookups on all constrained fields</li> <li>• Intelligent screen context management for easy navigation.</li> <li>• Fast, predictable response.</li> <li>• Much more.</li> </ul>
36.2. Customer Feedback	Customer feedback is very positive, including comparisons with other enterprise applications.
<b>37. System Reliability and Maintenance Requirements</b>	
37.1. Reliability / Redundancy	Uptime is a factor of the hardware purchased and the database backup schedule of the site. In addition the BlazeLIMS database design and automated query generator insures long term performance in the face of database growth with no need for DBA involvement in tuning, thus minimizing support costs. Project provisions may be made for hot spares using database shadowing features that are standard in SQL Server and Oracle.
37.2. Mean time between failures	Uptime is primarily a factor of the hardware purchased and the system and database backup schedule of the site. BlazeLIMS software has a track record of being extremely reliable and not causing failures. Rather, failures are usually related to hardware, networking or DBMS issues.
37.3. Manual work flow provisions during failure	BlazeLIMS provides hard copy reports and features that allow the design of an adequate manual workflow system in most cases.
37.4. Self-tests and diagnostics	BlazeLIMS provides proven error path logic, and numerous internal self-tests, traces and other diagnostics for use in troubleshooting problems, reducing problem solving turn-around times and costs.
37.5. Repair / Replace policy (software only)	For systems under support, Blaze Systems prioritizes problems according to impact on the operation and will supply patch updates as soon as possible where justified. Beyond that, repair and replacement is performed according to the standard release and upgrade procedures.

<b>Feature</b>	<b>BlazeLIMS Capability</b>
37.6. Time to repair (software only)	Timing and effort to repair are negotiated with the customer on an incident-by-incident basis. For the rare case where problems are critical to system operations, Blaze Systems guarantees a best effort dedication and has provided repair times ranging from 1-2 hours to 2-3 days. Beyond that, repair and replacement is performed according to the standard release and upgrade procedures.
37.7. Maintenance training level required	Blaze Systems normally requires that the customer provide a single point first level support person, capable of arranging operating system and network support from his local organization, and capable of performing preliminary LIMS troubleshooting in cooperation with laboratory personnel. This requires attendance at the LIMS training classes.
37.8. Software maintenance & updates	BlazeLIMS support includes software maintenance and distribution of software upgrades.
37.8.1. Frequency of updates	Blaze Systems updates its products with major releases approximately once per year and minor releases once per quarter. However, a site is not required to install an update for continued support provided they continue to run on supported versions of the operating system and DBMS.
37.8.2. Install new release in parallel for testing	Multiple versions of BlazeLIMS can be installed on a system. As a result, a new release can be run in parallel for testing. For mission critical systems, a second server installation should be purchased for parallel testing.
37.8.3. Migration of data to new release	BlazeLIMS provides an automated process for migrating a previous database into a new release by automatically generating the SQL scripts necessary to upgrade the database.
37.8.4. Documentation on software update	Blaze Systems provides release notes and new documentation on software updates.
37.8.5. Ease of update process	Blaze Systems is experienced with updating our customers and employs many methods and tools that make this process cheaper and less disruptive. This is achieved by configuration control and validation procedures, installation tools and flexibility and joint planning for success.
<b>38.Security</b>	
38.1. LIMS by group	A BlazeLIMS user is assigned to one of eight user types, and may also be assigned a number of fine-grained specific privileges within the user type. In addition, a user can be assigned to one or more Lab Groups, which limits his data entry to information associated with those Lab Groups.
38.2. LIMS by user	A BlazeLIMS user is assigned to one of eight user types, and may also be assigned a number of fine-grained specific privileges within the user type.

38.3.	LIMS by data type	BlazeLIMS allows access to data by type appropriately to each of the eight user types. For example, only administrators may view and modify all configuration data.
38.4.	LIMS by field	BlazeLIMS allows access to data by field appropriately to each of the eight user types and based on the current status of the data. For example, technicians may enter results, but not for tests or samples that have already been approved.
38.5.	By LIMS function	BlazeLIMS allows access to functions appropriately to each of the eight user types and based on the current status of the data. For example, technicians may not approve results.
38.6.	By OS system (mini/LAN)	BlazeLIMS access control is integrated with Windows security via Active Directory integration using either domain or local accounts for authentication, and may also employ security at the application level.
38.7.	By facility (physical security)	All application information and access is through the application and database servers, so physical security is assured.
38.8.	By network (WAN)	BlazeLIMS access control is integrated with Windows security via Active Directory integration using either domain or local accounts for authentication, and may also employ security at the application level.
38.9.	By electronic identification (passwords, badges, bar codes)	BlazeLIMS provides electronic identification by password that is authenticated by Windows security via Active Directory integration or by application level security. BlazeLIMS includes a special employee number in the User table that may also provide authentication. Special equipment such as badge readers may be used to authenticate the special employee number.
38.10.	By electronic signature (biometric verification, i.e. retina scan)	BlazeLIMS includes electronic signatures based on username/password combination.
38.11.	Automatic terminal time out	The BlazeLIMS Client includes an automatic terminal activity timeout feature that is configurable on a Work Station basis. The timeout can either exit or pause the application, and requires a username/password to be activated.
38.12.	Encryption	The BlazeLIMS thin client architecture allows use of Windows file encryption for all server files if desired. Encryption is also available for all client-server communications and BlazeLink instrument uploads.
<b>39. Vendor Rating</b>		Blaze Systems operates under a quality system derived from ISO 9000-3 and IEEE-730 standards and described in the Blaze Systems Quality Manual.
39.1.	Voice Support	Blaze Systems answers incoming phone calls in person. Calls are then directed to the appropriate technical support person.
39.2.	Modem Support	Blaze employs remote support via customer access portals as provided, where the customer's access control policy allows and support it. This allows a prompt and effective response to problem calls.

39.3. Help Desk Support	Blaze Systems provides a highly effective, responsive and personal Help Desk support. Calls are immediately vectored to the person most capable of handling the problem or most familiar with the user system and most problems are handles during the first call.
39.4. Installation Support	Blaze Systems provides Installation Support and has a published installation document.
39.5. Documentation	BlazeLIMS includes a Lab Manager Manual and a User Guide.
39.6. Established Software Development Standards	Blaze Systems operates under a quality system derived from ISO 9000-3 and IEEE-730 standards and described in the Blaze Systems Quality Manual
39.7. Form Change Control	BlazeLIMS executes form change control for all project and product documents.
39.8. Software Revision Control	BlazeLIMS executes software revision control for all elements of the software product.
39.9. Software Portability.	BlazeLIMS is supported on Windows client and server platforms.
39.10. Access to source code	BlazeLIMS source is available in the BlazeLIMS Development Environment. The site can purchase the BlazeLIMS Development Environment.
39.11. Quality and skills of staff	Blaze Systems has an experienced staff of software developers with extensive experience in developing commercial software. Curriculum vitae are available as part of RFP responses.
39.12. Quantity of support staff for customer support	At Blaze Systems, the Technical Support hotline is staffed with knowledgeable support people who are committed to answering your technical questions and helping to solve problems. Our Technical Support staff includes the developers of our BlazeLIMS products who have years of experience providing the best Technical Support in the LIMS industry.
39.13. Quantity of staff dedicated to R&D on future LIMS functions	Blaze Systems has the equivalent of 3 full time staff members dedicated to R&D on LIMS functions.
39.14. Ability of vendor to apply new technology to LIMS product	Blaze Systems has consistently incorporated newer technology into its product line. Blaze Systems is committed to the LIMS industry and to maintaining the state of the art of its technology.
39.15. Financial stability	Blaze Systems has been in business for 20 years and has long term support contracts with various customers.
39.16. Number of LIMS installed	Blaze Systems has installed over 130 BlazeLIMS systems.
39.17. Number of years in the LIMS business	Blaze Systems has been in the LIMS business for 18 years.

39.18. Meet GMP/GALP, NELAC, 21CFR or other regulatory requirements	BlazeLIMS meets GMP/GALP, NELAC and 21CFR requirements. BlazeLIMS supports all features necessary to operate a laboratory in GMP/GALP, NELAC and 21CFR11 compliance. Blaze Systems offers products and service to facilitate GMP validation. Blaze Systems operates under a quality system derived from ISO 9000-3 and IEEE-730 standards and described in the Blaze Systems Quality Manual.
39.19. Problem resolution time	Blaze Systems has a help desk that immediately responds to inquiries from its customers. Blaze Systems can often resolve problems within the same day.
39.20. Sales / support location	Blaze Systems' main office is in Newark, DE, USA.
<b>40. Cost</b>	To our knowledge, Blaze Systems is substantially less expensive than LIMS systems with equivalent functionality and capability from other suppliers. The BlazeLIMS costing model may be via one-time license or SaaS pricing, on a concurrent user basis. Blaze Systems can also host your server, provide full backup and restore capability. Blaze Systems will provide budgetary cost information at your request.
<b>41. Links to general purpose tools</b>	
41.1. Word Processing	Microsoft Word – OLE integration for display/edit/capture/reporting
41.2. Spreadsheet	Microsoft Excel – OLE integration for display/edit/capture/reporting.
41.3. Pop-up Calculator(s)	BlazeLIMS does not link to a pop-up calculator.
41.4. Statistical Analysis	NWA Quality Analyst – integrated via pushbutton access and data export.
41.5. Graphic Presentation	Microsoft Excel, Crystal Reports, and NQA for graphical presentations.
41.6. Reports	BlazeLIMS provides runtime linkages to Microsoft Excel, Microsoft Word, Microsoft Project, Crystal Reports, for reporting delivered as pdf, text, spreadsheet, xml, html, and output to viewers, printers, e-mail attachments, folders, fax, conveniently and properly directed to areas, clients, customers, internal lab users, external applications, etc. A comprehensive catalog of over 150 standard reports exists for every facet of laboratory operation. Provisions are made to easily customize these reports or provide additional reports and configure them into menus, buttons, events, scheduling, etc. Training is provided for Crystal Reports in the context of the BlazeLIMS schema and usage. The result is a highly flexible and powerful end-user environment for creating highly effective reports with minimal expenditures of time.

41.7. Email

BlazeLIMS provides integration with email via links to an SMTP server or Outlook. Email can be triggered by events as described in this document for work requests, samples, aliquots, inventory, instruments, etc. via configuration. Configuration can be conveniently provided via entities such as users, customers, clients, roles, distribution lists, and more. In addition, any report as described herein can be delivered as an attachment to email.