Form No. 233
7-78

VENDOR SURVEY FORM

DATE PREPARED _____

COMPANY SURVEYED		
ADDRESS		
CITY	STATE	ZIP CODE
TELEPHONE AC ( )	TELEX	

NOTICE:

I (We) certify that the information contained in the attached survey form is accurate and complete as of the date indicated. Where trade secret or other proprietary information is involved, the person interviewed has initialed those responses not verified by the interviewer. All information obtained will be kept confidential. A corporate officer of the company surveyed will review all responses made at the time of survey. This survey has been made with the permission of the company surveyed.

SIGNATURE	TITLE	LOCATION
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PART I — GENERAL INFORMATION

ANNUAL SALES	YEARS IN BUSINESS	PRIVATELY OWNED	SUBSIDIARY, DIVISION, FACILITY OF

OTHER PLANT LOCATIONS _____

LIST MAJOR CUSTOMERS _____ TYPE OF CONTRACT _____

NOT AVAILABLE ☐ NOT AVAILABLE ☐

LIST COMPANY MANAGEMENT

NAME	TITLE	INTERVIEWED

PRODUCTS FOR WHICH SURVEY WAS PERFORMED *(ATTACH LABELING)* _____

TOTAL NUMBER EMPLOYEES _____ LABOR RATIO OF SUPERVISORS _____ TO PRODUCTION PERSONNEL _____

WORK SCHEDULE HOURS _____ NUMBER SHIFTS _____ DAYS PER WEEK _____

ARE TRAINING PROGRAMS FOR PERSONNEL UTILIZED Yes☐ No☐

FACILITY

NUMBER BUILDINGS ON SITE _____ TYPE (SINGLE/MULTISTORY; WOOD/BRICK/BLOCK/STEEL) _____

LOCATION IN INDUSTRIAL PARK☐ URBAN☐ SUBURBAN☐ RURAL☐ EQUIPMENT OWNED OR LEASED _____

SQUARE FOOTAGE IN MANUFACTURING _____ ADMINISTRATION _____ STORAGE _____ ENGINEERING, R&D _____

LIST PROCESS CAPABILITIES AND SPECIAL MANUFACTURING EQUIPMENT ESSENTIAL TO MATERIALS BEING PROCURED.

1. _____
2. _____
3. _____
4. _____
5. _____

LIST MANUFACTURING DONE BY OUTSIDE SOURCES (SUBASSEMBLY, PACKAGING, KIT ASSEMBLY, ETC.)

1. _____
2. _____
3. _____
4. _____
5. _____

IS THERE A DOCUMENT/PROCESS FLOW MANUAL OUTLINING ALL MANUFACTURING STEPS, RECORDS, AND CONTROLS FROM RAW MATERIALS TO FINISHED PRODUCT (AS REQUIRED FOR SOME GOVERNMENT CONTRACTS) Yes☐ No☐

DOES THE MANUFACTURER HAVE LIABILITY INSURANCE Yes☐ No☐

INSURED BY _____

HAS THE MANUFACTURER BEEN INSPECTED BY ANY STATE OR FEDERAL AGENCIES WITHIN THE LAST TWO YEARS Yes☐ No☐

NAME OF AGENCIES

WERE RECALLS INVOLVED Yes☐ No☐

COMMENTS _____

PART II — RAW MATERIALS AND COMPONENTS CONTROL

PURCHASING

IS QUALIFICATION BASED ON WRITTEN SPECIFICATIONS, AND APPROVAL OF VENDOR SOURCES Yes☐ No☐

ARE REJECT/ACCEPT LIMITS SHOWN Yes☐ No☐

IS APPROVAL BASED ON

QUALITY HISTORY CARDS☐ SUPPLIERS CERTIFICATE☐ ON SITE SURVEY☐ OWN QC TESTING☐

OTHER _____

ARE SPECIFICATION CHANGES REVIEWED AND SIGNED OFF BY QC PERSONNEL Yes☐ No☐

TESTING

ARE WRITTEN TEST PROCEDURES IN USE Yes☐ No☐

TEST RESULTS ON FILE Yes☐ No☐

SAMPLING PLAN USED 100%☐ MIL SPEC☐ AQL☐ RANDOM☐

OTHER _____

DO TEST RESULTS INDICATE QUANTITY SAMPLED☐ METHOD OF ANALYSIS☐ DATE & SIGNATURE OF ANALYST☐ SAMPLE TRACEABILITY☐

IS THERE A RETENTION SAMPLE SYSTEM FOR RAW MATERIALS/COMPONENTS Yes☐ No☐

IN PLANT CONTROL

MATERIAL ASSIGNED ALPHA-NUMERIC OR IDENTIFYING MARK FOR EACH INCOMING LOT Yes☐ No☐

MATERIAL VISIBLY MARKED AS

SAMPLED☐ APPROVED☐ REJECTED☐ NOT MARKED☐

INVENTORY LOG OR RECORD KEPT Yes☐ No☐

STORAGE AREA SEPARATE Yes☐ No☐

SEGREGATED WITHIN STORAGE AREA Yes☐ No☐

STOCK ROTATION (FIFO) SYSTEM USED Yes☐ No☐

AUTHORIZED CUSTODIAN CONTROL Yes☐ No☐

GENERAL HOUSEKEEPING NEAT AND ORDERLY Yes☐ No☐

REJECTED MATERIALS ARE:

CLEARLY IDENTIFIED Yes☐ No☐

PHYSICALLY SEGREGATED Yes☐ No☐

PART III — MANUFACTURING

MASTER PRODUCTION RECORDS

IS THERE A SINGLE CONTROLLED FILE OF MASTER RECORDS FOR EACH PRODUCT Yes☐ No☐

BATCH SHEETS☐ LINE ENGINEERING, ASSEMBLY DRAWINGS☐

OTHER _____

ARE THESE MASTER RECORDS SIGNED AND DATED Yes☐ No☐

DOUBLE SIGNATURE☐ REVISION DATES☐

ARE THE PROCESS, ASSEMBLY, OR MANUFACTURING STEPS FULLY DESCRIBED:

IN THE MASTER PRODUCTION RECORD Yes☐ No☐

IN A SEPARATE DOCUMENT OR RECORD Yes☐ No☐

IS THERE A MASTER DOCUMENT TO INDICATE:

QC POINTS FOR IN-PROCESS MANUFACTURING Yes☐ No☐

TYPE OF TEST OR INSPECTION TO BE MADE Yes☐ No☐

METHOD OF MEASUREMENT Yes☐ No☐

WHO PERFORMS TEST OR INSPECTION Yes☐ No☐

LEVEL OF ACCEPT/REJECT (LIMITS) Yes☐ No☐

FOR MANUFACTURING, PROCESSING, SUBASSEMBLY, OR PACKAGING DONE BY OUTSIDE SOURCES, ARE THERE:

MASTER PRODUCTION RECORDS Yes☐ No☐

QC SPECIFICATIONS AND METHODS RECORDS Yes☐ No☐

OUTSIDE SOURCES NOT USED Yes☐ No☐

PRODUCTION AREA

IS THE WORK FLOW ORGANIZED Yes☐ No☐

DISTINCT STAGING AREA FOR RAW MATERIALS OR COMPONENTS USED IN MANUFACTURING Yes☐ No☐

PRODUCTION OR ASSEMBLY LINES SEGREGATED Yes☐ No☐

GENERAL HOUSEKEEPING AND ENVIRONMENTAL FACTORS GOOD Yes☐ No☐

WRITTEN PROCEDURES FOR PLANT SANITATION AVAILABLE Yes☐ No☐

PRODUCTION EQUIPMENT

MAINTENANCE OR SERVICE RECORDS AVAILABLE Yes☐ No☐

CALIBRATION RECORDS KEPT ON PERIODIC BASIS Yes☐ No☐

MEANS OF READILY IDENTIFYING TYPE AND STAGE OF PROCESSING BEING DONE ON THE EQUIPMENT Yes☐ No☐

PRODUCTION RECORDS

ARE PRODUCTION DOCUMENTS COLLECTED AND FILED Yes☐ No☐

KEPT _____(YEARS)

COMPLETE HISTORY☐ LABELING SAMPLES INCLUDED☐ TRACEABILITY BY LOT OR SERIAL NUMBER☐

PARTIAL HISTORY☐

PACKAGING

ARE FINISHED GOODS PACKAGING OPERATIONS SEGREGATED Yes☐ No☐

UNDER SUPERVISED CONTROL Yes☐ No☐

LABEL RECORDS KEPT Yes☐ No☐

PRE-LABEL COUNT☐ RECONCILIATION☐

ARE FINSIHED GOODS PROPERLY IDENTIFIED, LABELED, AND STORED Yes☐ No☐

PRIOR TO RELEASE☐ AFTER RELEASE☐

REJECTED MATERIALS

ARE THERE WRITTEN PROCEDURES FOR DISPOSING OF OR REWORKING REJECTED ITEMS Yes☐ No☐

ARE REJECTED PRODUCTS HELD IN QUARANTINE PENDING FINAL DISPOSAL Yes☐ No☐

SEGREGATED AREA☐ SPECIAL MARKINGS☐

RETENTION SAMPLES

ARE SAMPLES OF FINISHED GOODS RETAINED Yes☐ No☐

FROM EACH PRODUCTION RUN☐

IN A SEPARATE CONTROLLED AREA☐

IN THE SAME CONTAINER/CLOSURE SYSTEM IN WHICH THEY ARE SOLD☐

IN CONTAINERS DIFFERENT FROM UNIT AS SOLD☐

KEPT FOR A PERIOD OF _____(YEARS)

WRITTEN LOG OR FILE☐

STERILE COMPONENTS *(IF APPLICABLE)*

ARE THERE PROCEDURES FOR ESTABLISHING AND MAINTAINING ASEPTIC CONDITIONS Yes☐ No☐

ARE METHODS FOR ROUTINE AUDITING OF STERILE AREAS USED Yes☐ No☐

ARE THERE PROCEDURES FOR WORKING IN STERILE AREAS Yes☐ No☐

FOR CLEANING AND STERILIZATION OF EQUIPMENT Yes☐ No☐

FOR BULK AND FINAL PRODUCT STERILITY TESTING Yes☐ No☐

IS PROCESS STERILITY FOR EACH RUN DOCUMENTED IN THE PRODUCTION RECORDS Yes☐ No☐

STERILE PROCESS USED

ETO☐ RADIATION☐ STEAM☐ FILTRATION☐

CHEMICAL☐ OTHER _____

PART IV — QUALITY CONTROL/ASSURANCE

ORGANIZATION AND FUNCTION

DOES THE QUALITY CONTROL-INSPECTION GROUP REPORT DIRECTLY TO THE TOP, INDEPENDENT OF PRODUCTION, MARKETING, OR OTHER ORGANIZATION GROUPS WITHIN THE MANUFACTURING COMPANY. (SEE COMPANY ORGANIZATION CHART) Yes☐ No☐

DOES THE QUALITY CONTROL-INSPECTION GROUP HAVE FULL AUTHORITY TO WITHHOLD SHIPMENT OR FURTHER PRODUCTION OF REJECTED ITEMS Yes☐ No☐

ARE THE QUALITY CONTROL PROCEDURES:

IN A FORMAL WRITTEN DOCUMENT Yes☐ No☐

REVISED ON A PERIODIC BASIS Yes☐ No☐

DOES THE QUALITY CONTROL/ASSURANCE-INSPECTION GROUP HAVE:

ADEQUATE EDUCATION, TRAINING OR EXPERIENCE Yes☐ No☐

UNDERSTANDING OF THEIR FUNCTION Yes☐ No☐

OTHER _____

OPERATIONS

ARE STAMPS, TAGS, MARKERS, ETC., USED TO VERIFY INSPECTION ACTIVITY Yes☐ No☐

ARE THE MARKINGS USED TRACEABLE TO AN INDIVIDUAL INSPECTOR Yes☐ No☐

ARE PRODUCTION SAMPLES FOR QC TESTING:

ADEQUATELY IDENTIFIED AS TO SOURCE Yes☐ No☐

RECORDED SOMEWHERE AT TIME OF SAMPLING Yes☐ No☐

ENTERED ON FILED TEST REPORT Yes☐ No☐

WRITTEN SAMPLING PLAN BASED ON:

100%☐ MIL SPEC☐ AQL☐ RANDOM☐

IS THE PRODUCT USED TESTED PRIOR TO FINAL RELEASE Yes☐ No☐

ARE OUTSIDE SOURCES USED FOR PRODUCTION TESTING Yes☐ No☐

UNDER FORMAL CONTRACT☐

USE TEST PROTOCOLS OR WRITTEN PROCEDURES☐

COPIES IN THE MANUFACTURING FILES☐

FACILITY REGISTERED OR LICENSED BY ANY FEDERAL, STATE OR PROFESSIONAL AGENCY☐

OUTSIDE TEST RESULTS FILED BY THE MANUFACTURER☐

IS THERE A FORMAL QUALITY ASSURANCE PROGRAM INVOLVING PERFORMANCE TESTING OF THE PRODUCT(s) AFTER RELEASE Yes☐ No☐

PART V — CUSTOMER COMPLAINTS AND RECALL CAPABILITIES

CUSTOMER COMPLAINTS

IS THERE AN ORGANIZED COMPLAINT FILE Yes☐ No☐

DOES EACH COMPLAINT STATE:

NATURE OF COMPLAINT☐

RESPONSE TO CUSTOMER (REPAIR, REFUND, REPLACE)☐

FURTHER CORRECTIVE/PREVENTIVE ACTION BY MANUFACTURER☐

COMPLAINT FILES KEPT FOR _____ (YEARS)

IS THERE A PERIODIC REVIEW OF COMPLAINT FILES FOR TRENDS Yes☐ No☐

IS THE REVIEW FILE AS A WRITTEN SUMMARY Yes☐ No☐

IS THERE A GROUP OR INDIVIDUAL ASSIGNED TO HANDLE CUSTOMER INQUIRIES AND FOLLOW UP ON COMPLAINTS Yes☐ No☐

ARE PRODUCT DEFECTS VERIFIED BY MANUFACTURER THROUGH TESTING Yes☐ No☐

WAS REVIEW OF COMPLAINT FILES FOR SURVEY PRODUCT MADE Yes☐ No☐

RECALL CAPABILITIES

IS THERE A COMPANY RECALL PLAN Yes☐ No☐

SHOWS HOW DECISIONS ARE MADE AND BY WHOM☐

HOW RECALL WILL BE ACCOMPLISHED☐

INSTRUCTIONS FOR RECOVERY AND ACCOUNTABILITY OF RECALLED PRODUCT☐

DO SHIPPING OR DISTRIBUTION RECORDS ON FILE SHOW:

CUSTOMER OR DISTRIBUTOR NAME AND ADDRESS Yes☐ No☐

DATE OF SHIPMENTS AND QUANTITY SHIPPED Yes☐ No☐

LOT OR SERIAL NUMBER OF PRODUCT SHIPPED Yes☐ No☐

DISTRIBUTION RECORDS ARE MAINTAINED _____(YEARS)

DISTRIBUTION RECORDS ARE STORED AS:

COMPUTER LISTING☐

MICROFILM/MICROFICHE☐

MANUAL CARD/PAPER FILES☐

PART VI — REGULATORY COMPLIANCE

IS THE PLANT REGISTERED AS A DEVICE MANUFACTURER Yes☐ No☐

ARE THE SURVEY PRODUCT(S) LISTED WITH BUREAU OF MEDICAL DEVICES Yes☐ No☐

ARE ALL NECESSARY APPROVALS FOR MARKETING PRODUCTS AVAILABLE Yes☐ No☐

IS THERE A FILE WITH PAST AND CURRENT LABELING FOR EACH SURVEY PRODUCT Yes☐ No☐

IS THERE A FORMAL AUDITING PROGRAM OF THE QC OPERATION. IF SO, DONE BY WHOM Yes☐ No☐

LIST OF ATTACHMENTS AND COMMENTS