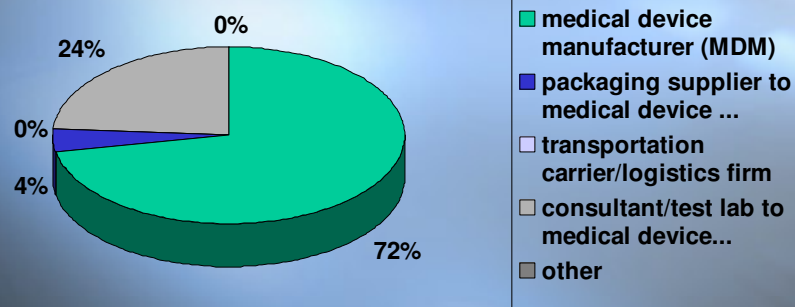
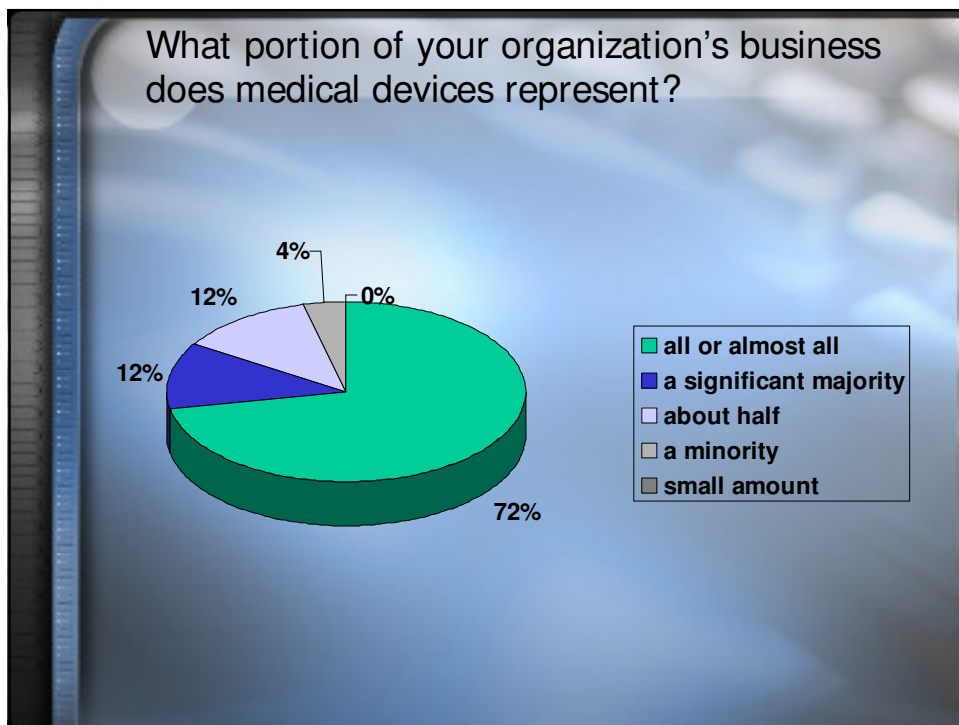
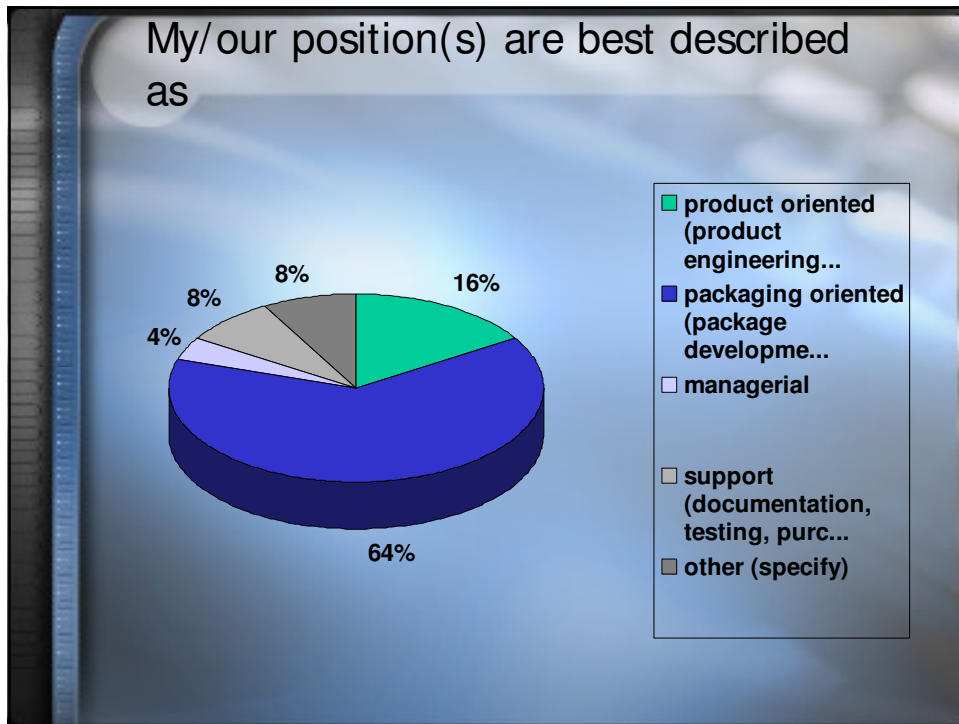


Results

- 85+ original contacts
- 60+ questionnaires distributed
- 25 returned
- Results analyzed
- Report sent to all participants
- IoPP Medical Device Committee will discuss results and make recommendations.

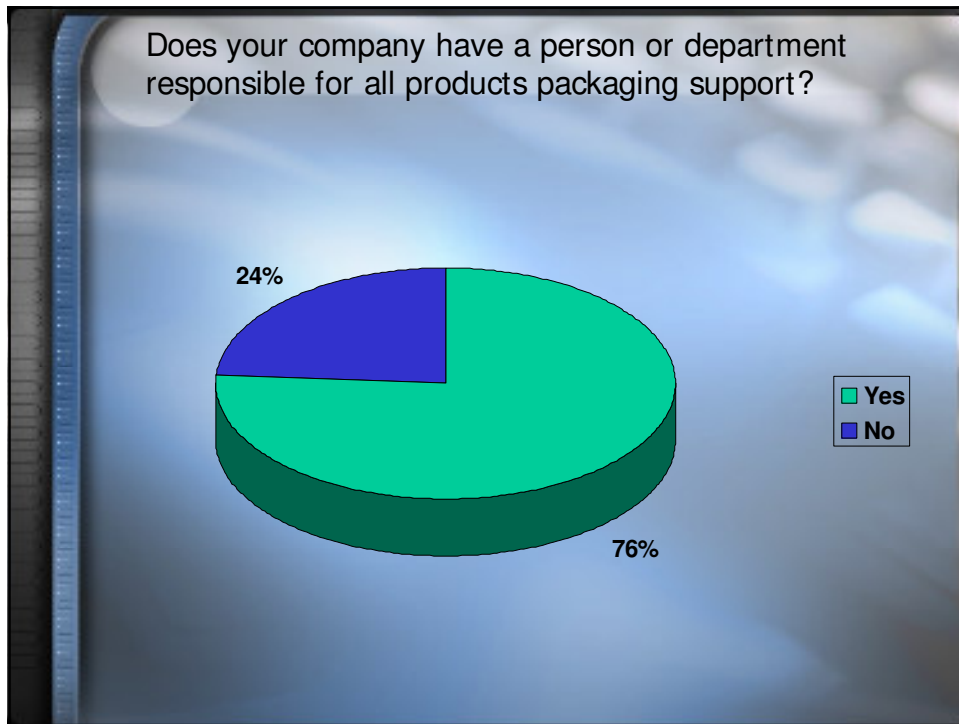
The type of organization is

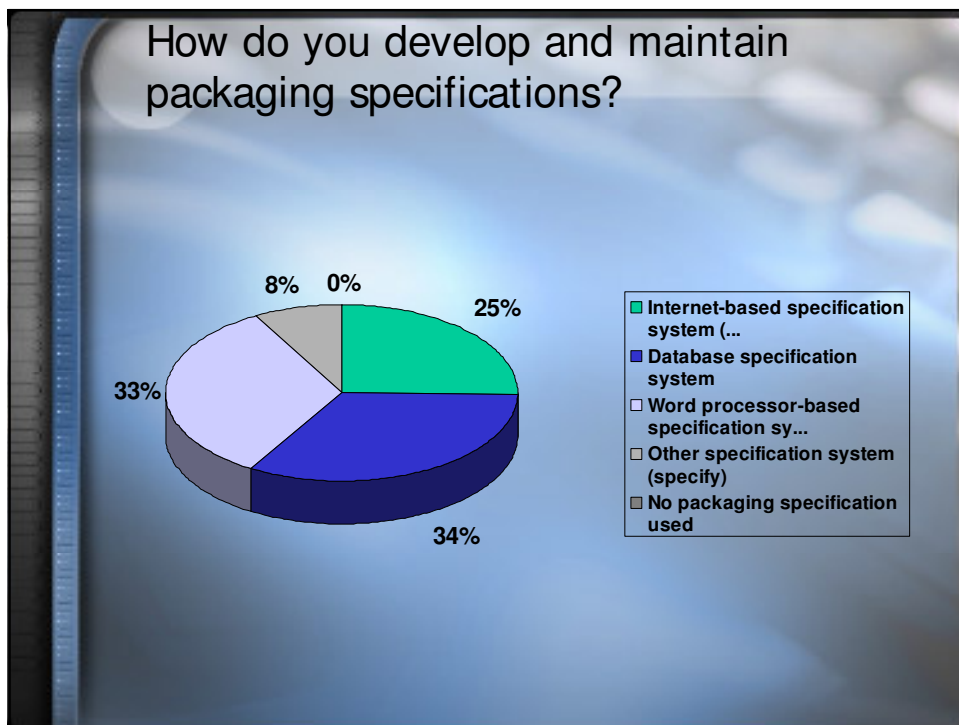
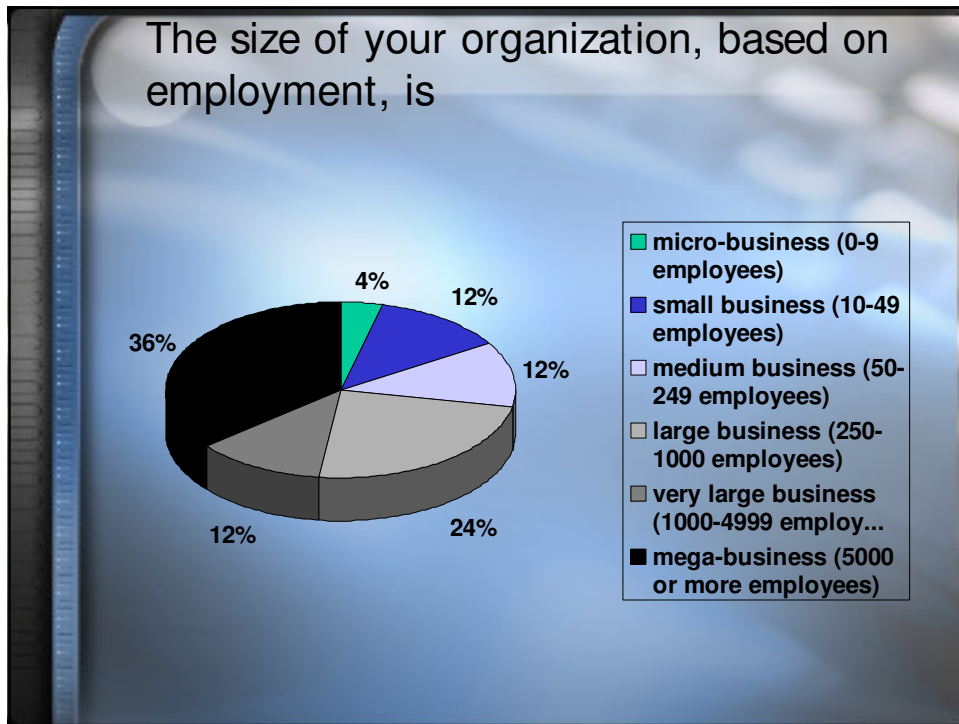


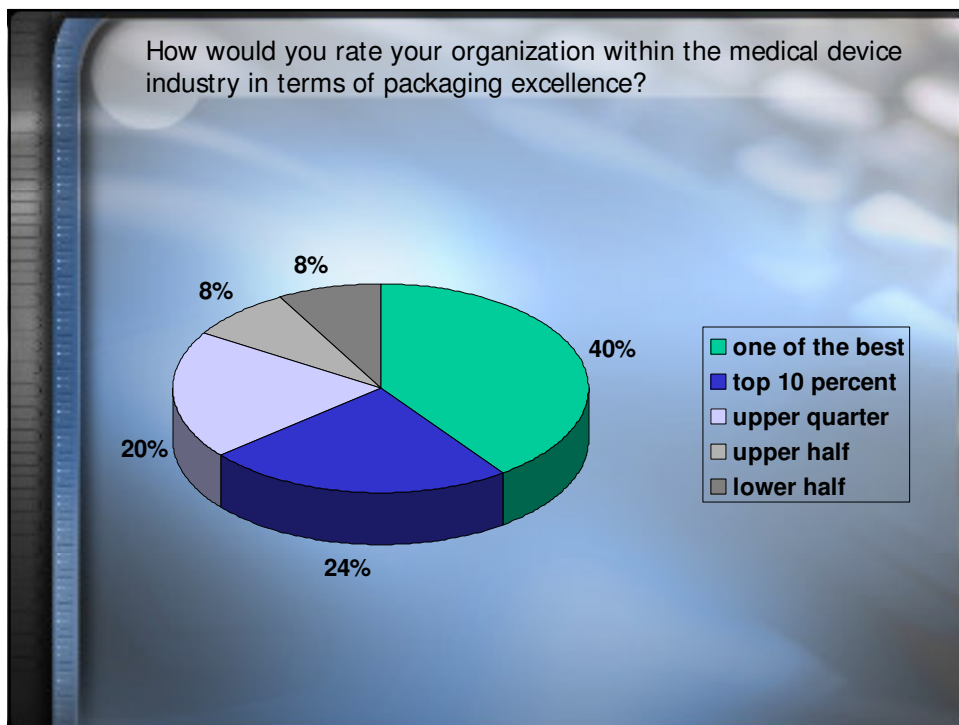
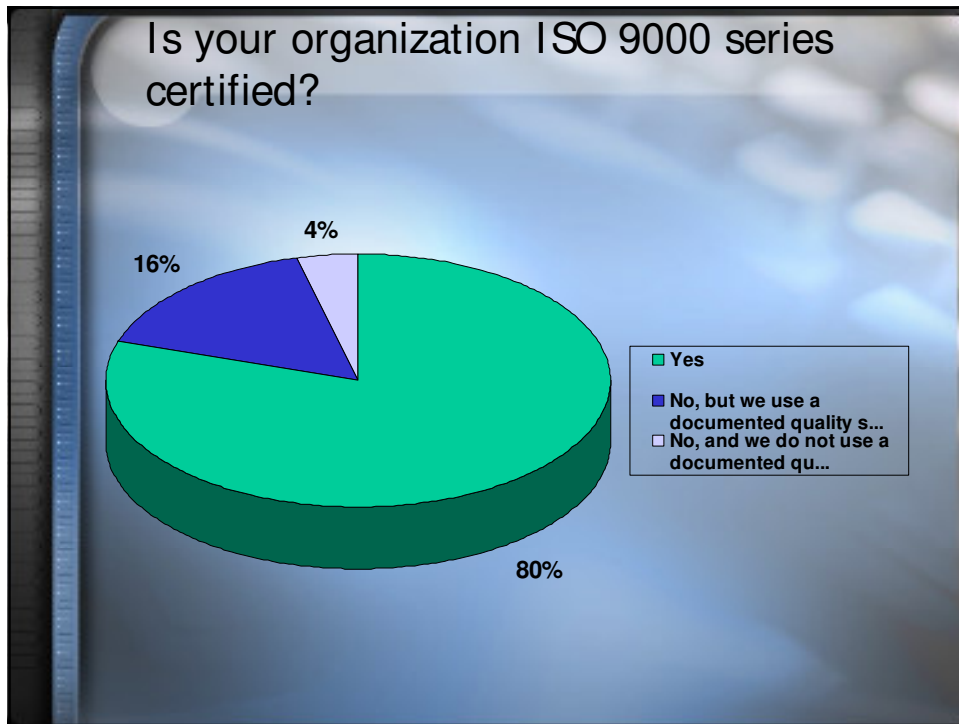


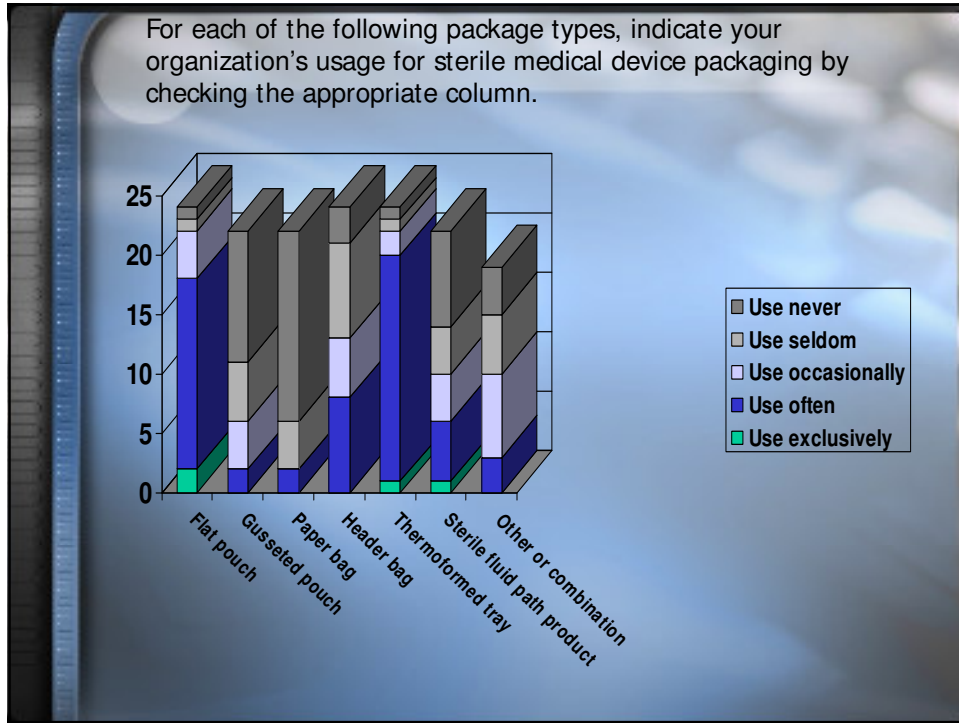


Choice	Count	Percent of Sample
AAMI/ISO	18	72.0%
AdvaMed	8	32.0%
ASQ	14	56.0%
ASTM	18	72.0%
IoPP	21	84.0%
ISTA	11	44.0%
NIPHLE	0	0.0%
SME	8	32.0%
Other (specify)	2	8.0%

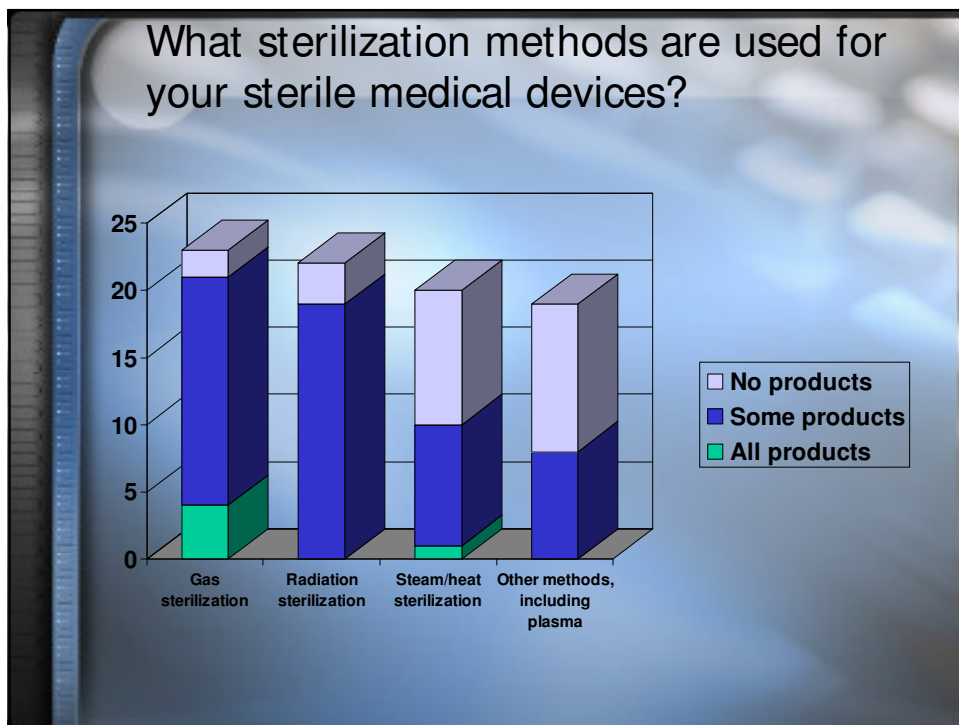
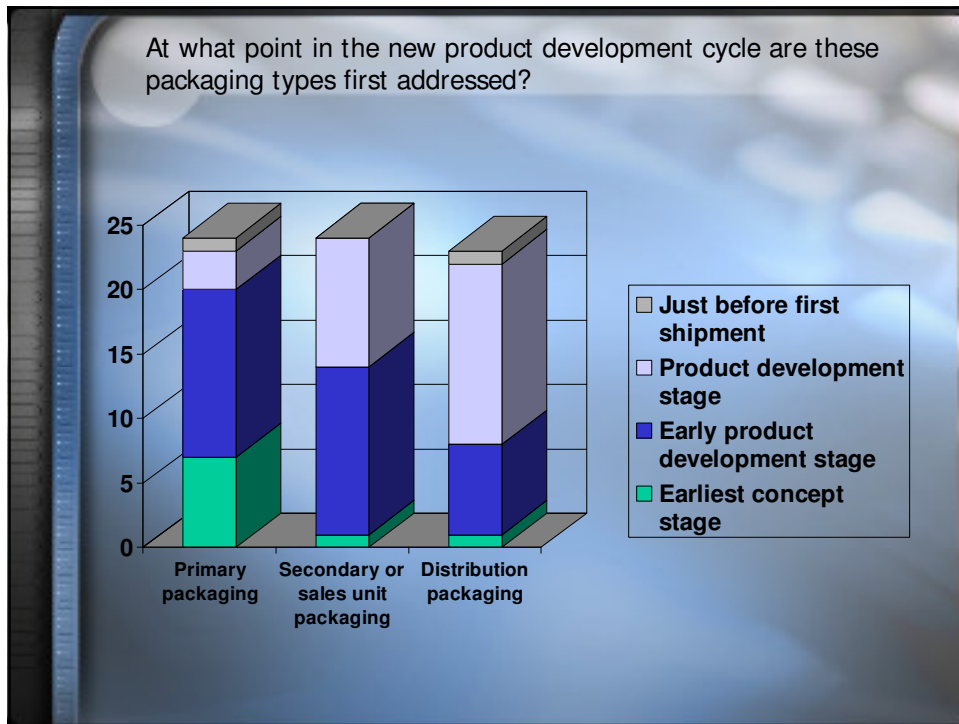


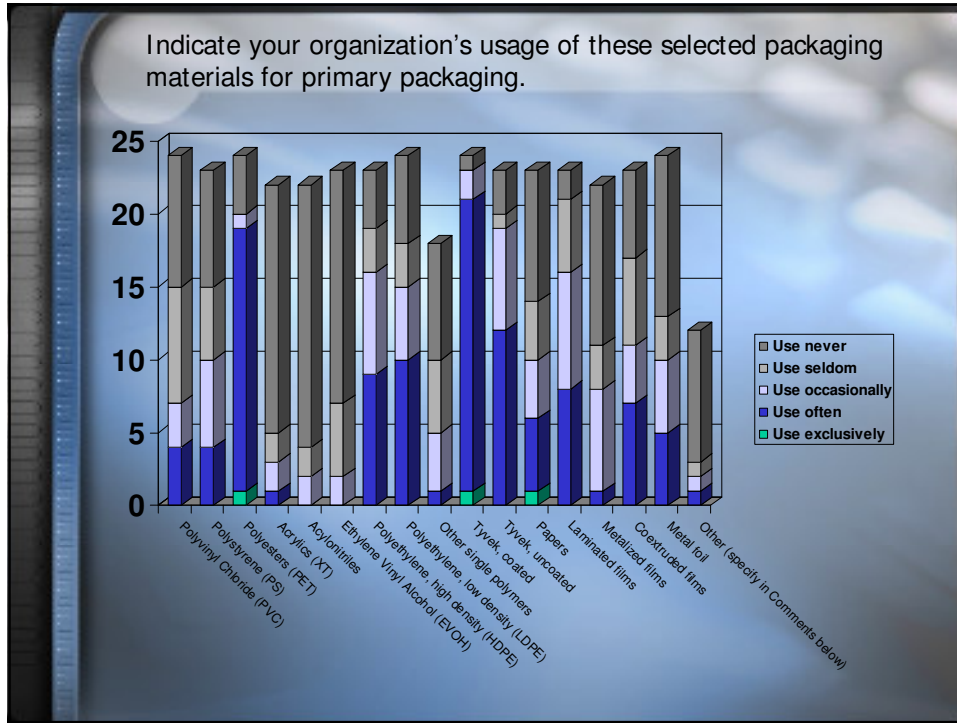




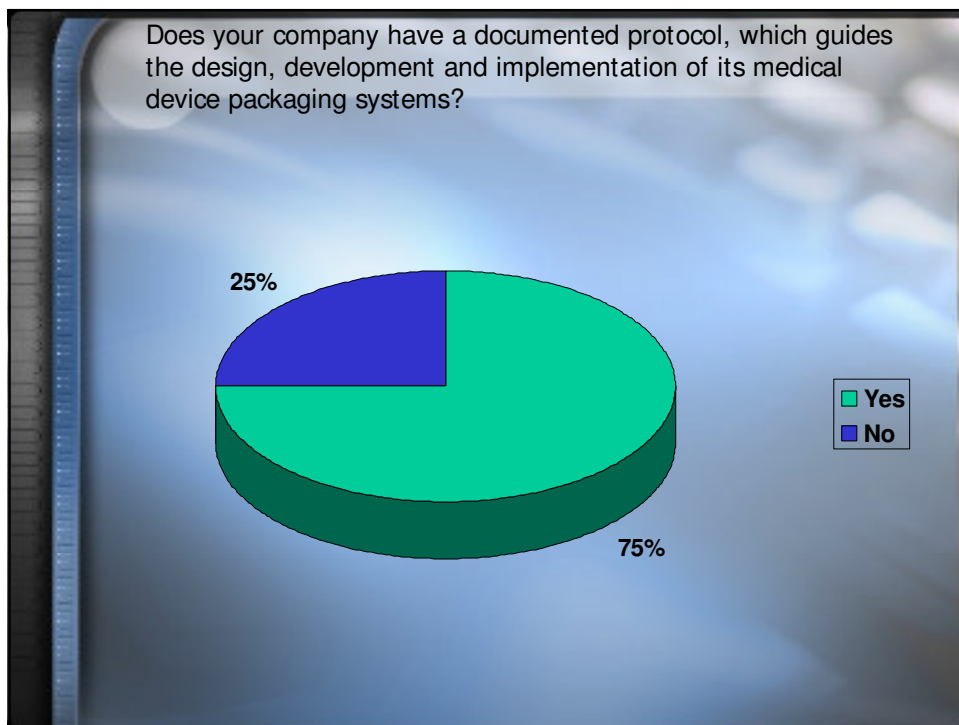
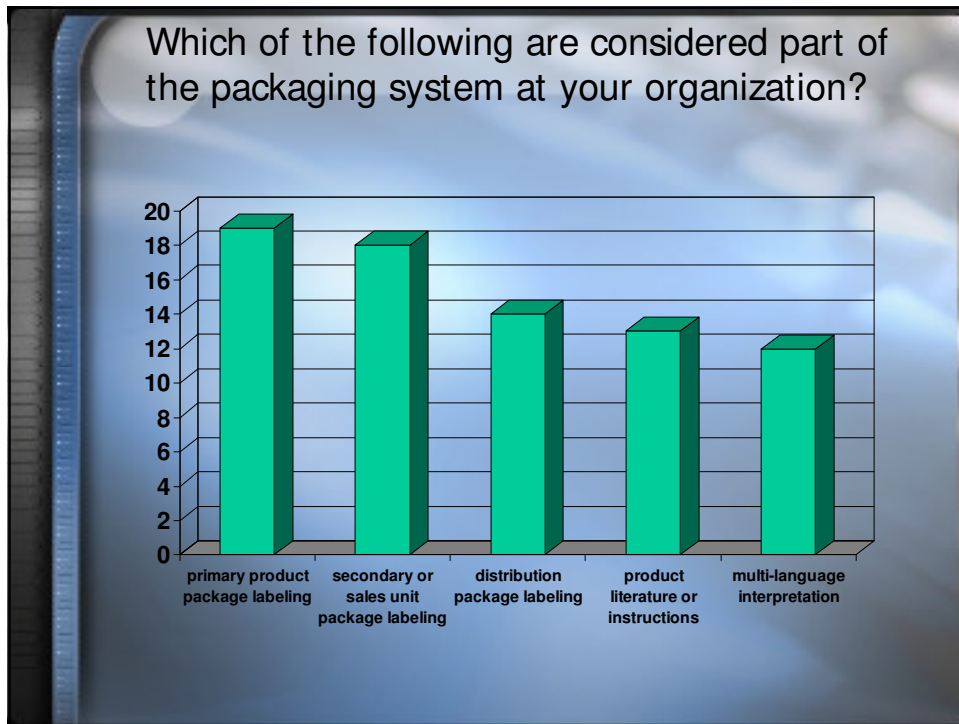


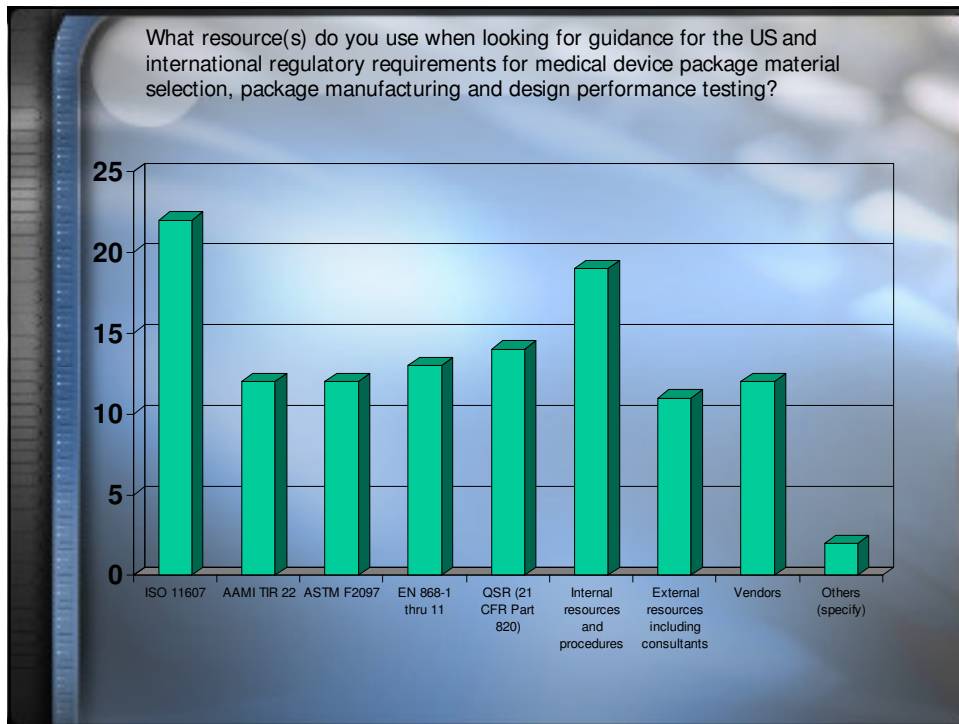
Topic	Use exclusively	Use often	Use occasionally	Use seldom	Use never
Flat pouch	2	16	4	1	1
Gusseted pouch	0	2	4	5	11
Paper bag	0	2	0	4	16
Header bag	0	8	5	8	3
Thermoformed tray	1	19	2	1	1
Sterile fluid path product	1	5	4	4	8
Other or combination	0	3	7	5	4



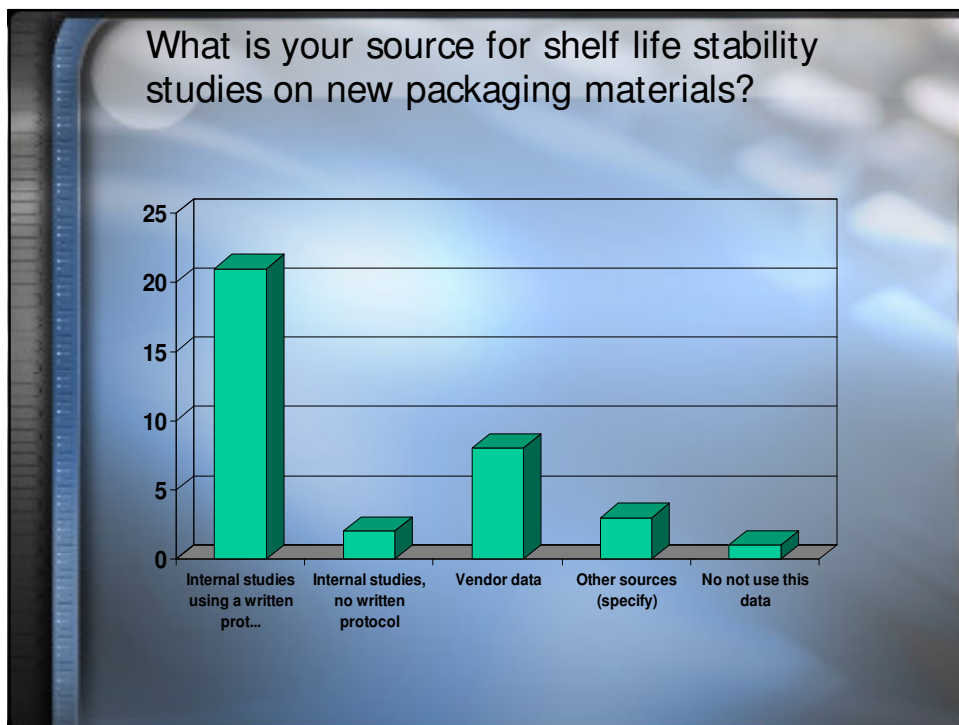
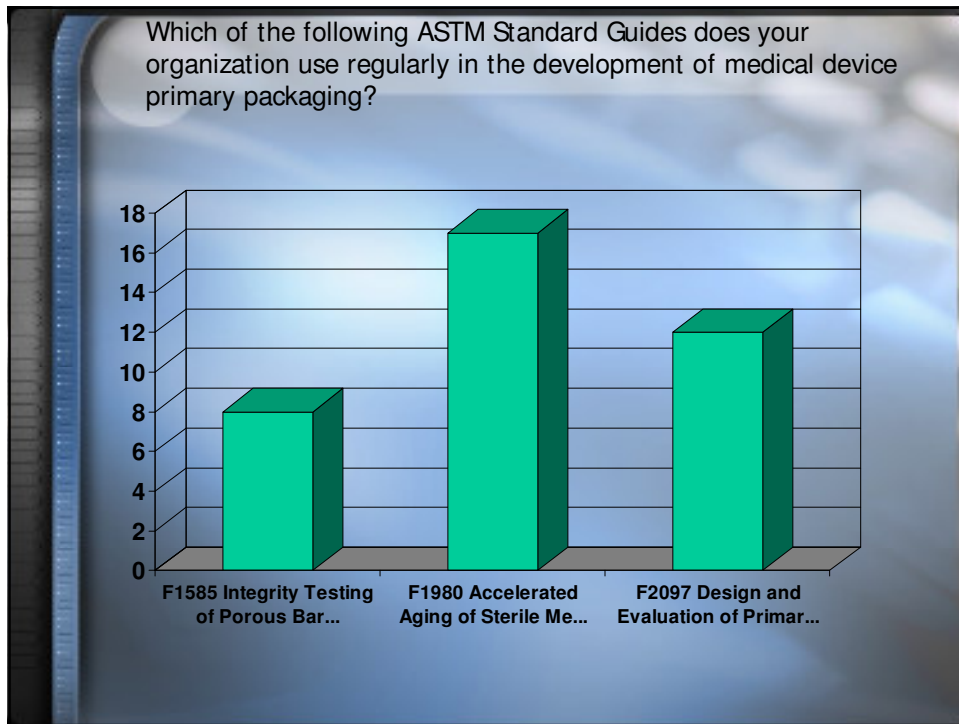


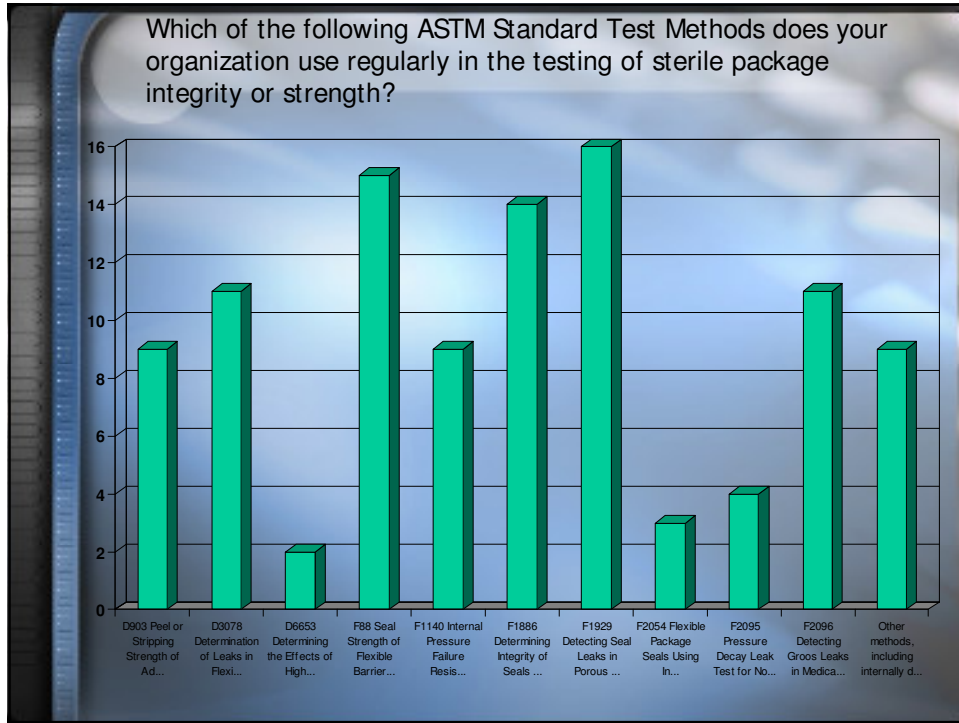
Topic	Use exclusively	Use often	Use occasionally	Use seldom	Use never
Polyvinyl Chloride (PVC)	0	4	3	8	9
Polystyrene (PS)	0	4	6	5	8
Polyesters (PET)	1	18	1	0	4
Acrylics (XT)	0	1	2	2	17
Acrylonitriles	0	0	2	2	18
Ethylene Vinyl Alcohol (EVOH)	0	0	2	5	16
Polyethylene, high density (HDPE)	0	9	7	3	4
Polyethylene, low density (LDPE)	0	10	5	3	6
Other single polymers	0	1	4	5	8
Tyvek, coated	1	20	2	0	1
Tyvek, uncoated	0	12	7	1	3
Papers	1	5	4	4	9
Laminated films	0	8	8	5	2
Metalized films	0	1	7	3	11
Coextruded films	0	7	4	6	6
Metal foil	0	5	5	3	11
Other (specify in Comments below)	0	1	1	1	9



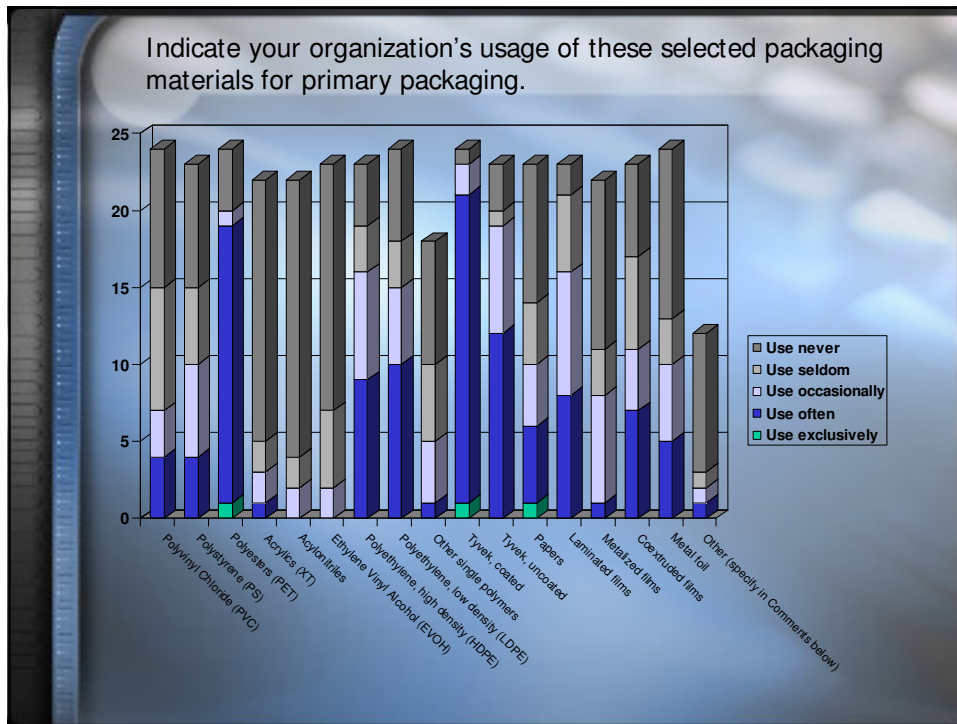


Choice	Count	Percent of Sample
ISO 11607	22	88.0%
AAMI TIR 22	12	48.0%
ASTM F2097	12	48.0%
EN 868-1 thru 11	13	52.0%
QSR (21 CFR Part 820)	14	56.0%
Internal resources and procedures	19	76.0%
External resources including consultants	11	44.0%
Vendors	12	48.0%
Others (specify)	2	8.0%

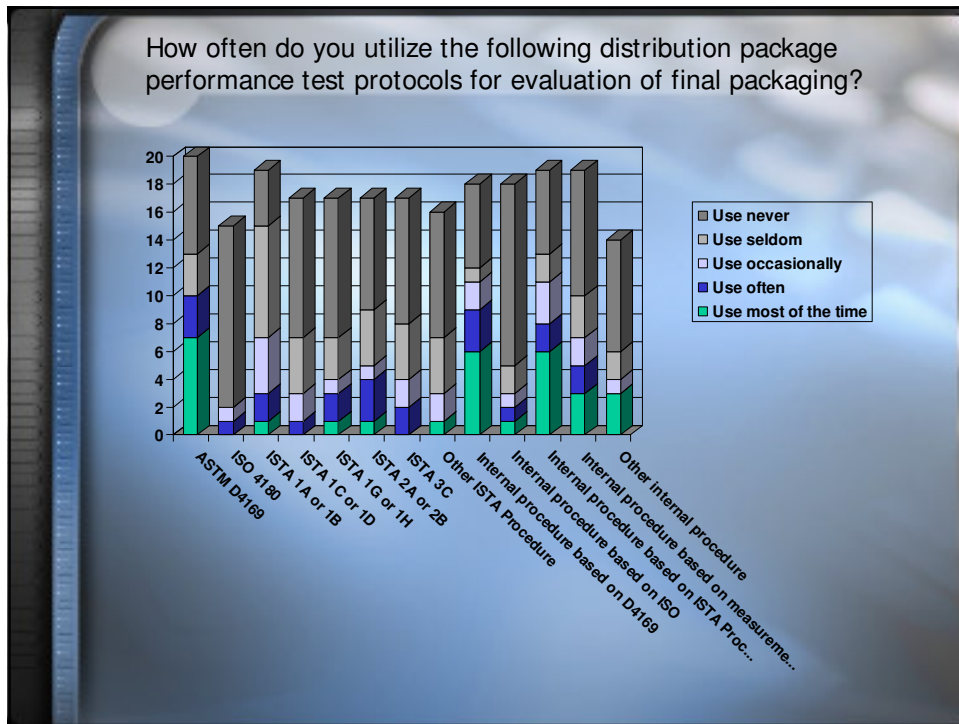




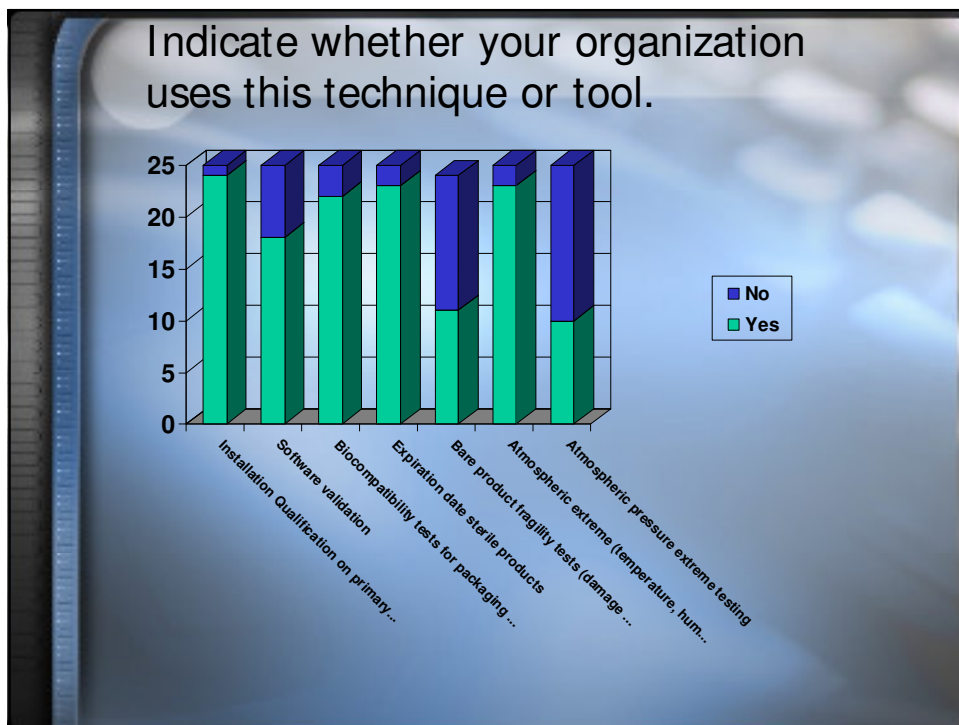
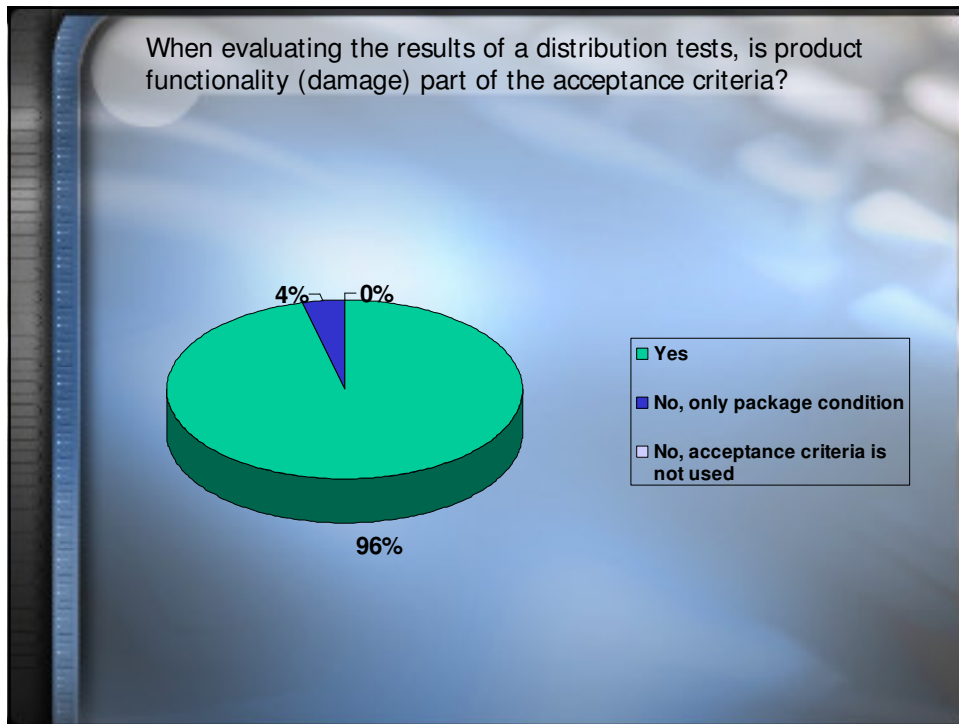
Choice	Count	Percent of Sample
D903 Peel or Stripping Strength of Adhesive Bonds	9	36.0%
D3078 Determination of Leaks in Flexible Packaging by Bubble Emission	11	44.0%
D6653 Determining the Effects of High Altitude on Packaging Systems by Vacuum Method	2	8.0%
F88 Seal Strength of Flexible Barrier Materials	15	60.0%
F1140 Internal Pressure Failure Resistance of Unrestrained Packages for Medical Applications	9	36.0%
F1886 Determining Integrity of Seals for Medical Packaging by Visual Inspection	14	56.0%
F1929 Detecting Seal Leaks in Porous Medical Packaging by Die Penetration	16	64.0%
F2054 Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates	3	12.0%
F2095 Pressure Decay Leak Test for Nonporous Packaging With and Without Restraining Plates	4	16.0%
F2096 Detecting Gross Leaks in Medical Packaging by Internal Pressurization (bubble Test)	11	44.0%
Other methods, including internally developed procedures	9	36.0%

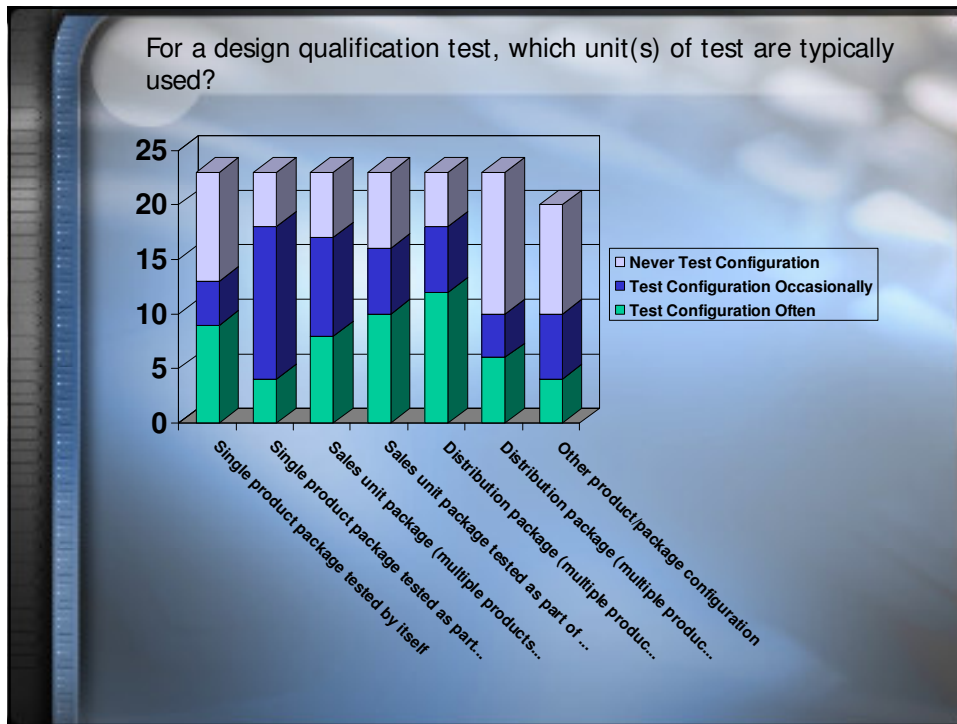


Topic	Use exclusively	Use often	Use occasionally	Use seldom	Use never
Polyvinyl Chloride (PVC)	0	4	3	8	9
Polystyrene (PS)	0	4	6	5	8
Polyesters (PET)	1	18	1	0	4
Acrylics (XT)	0	1	2	2	17
Acrylonitriles	0	0	2	2	18
Ethylene Vinyl Alcohol (EVOH)	0	0	2	5	16
Polyethylene, high density (HDPE)	0	9	7	3	4
Polyethylene, low density (LDPE)	0	10	5	3	6
Other single polymers	0	1	4	5	8
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Tyvek, uncoated	0	12	7	1	3
Papers	1	5	4	4	9
Laminated films	0	8	8	5	2
Metalized films	0	1	7	3	11
Coextruded films	0	7	4	6	6
Metal foil	0	5	5	3	11
Other (specify in Comments below)	0	1	1	1	9

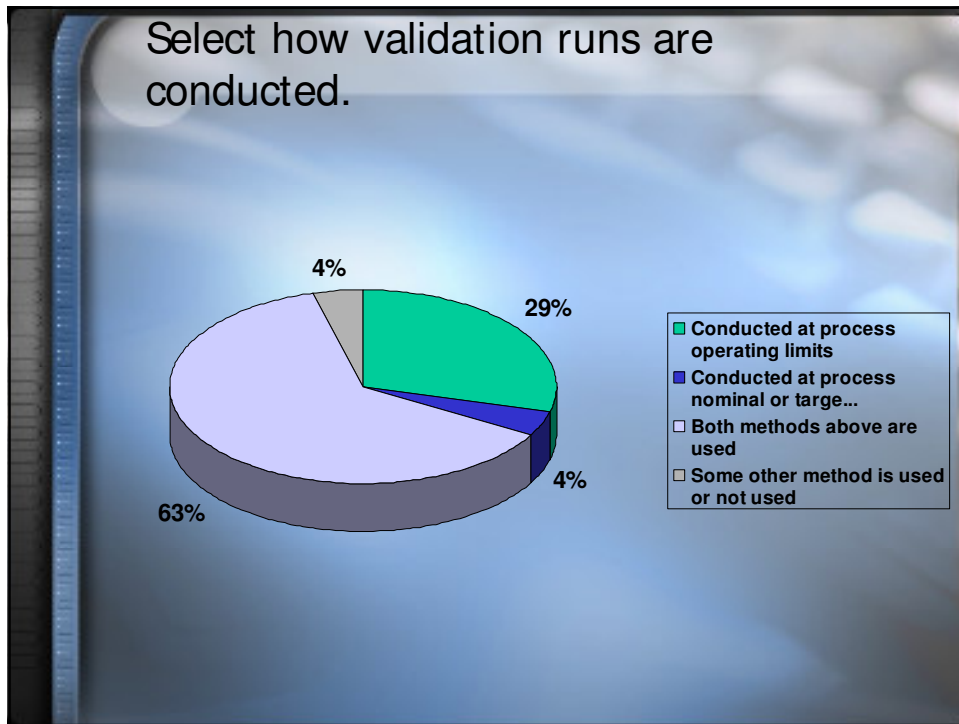


Topic	Use most of the time	Use often	Use occasionally	Use seldom	Use never
ASTM D4169	7	3	0	3	7
ISO 4180	0	1	1	0	13
ISTA 1A or 1B	1	2	4	8	4
ISTA 1C or 1D	0	1	2	4	10
ISTA 1G or 1H	1	2	1	3	10
ISTA 2A or 2B	1	3	1	4	8
ISTA 3C	0	2	2	4	9
Other ISTA Procedure	1	0	2	4	9
Internal procedure based on D4169	6	3	2	1	6
Internal procedure based on ISO	1	1	1	2	13
Internal procedure based on ISTA Procedure	6	2	3	2	6
Internal procedure based on measurement of distribution hazards (drop, vibration, compression, atmospheric)	3	2	2	3	9
Other internal procedure	3	0	1	2	8





Topic	Test Configuration Often	Test Configuration Occasionally	Never Test Configuration
Single product package tested by itself	9	4	10
Single product package tested as part of a mixed load (in master shipper)	4	14	5
Sales unit package (multiple products) tested by itself	8	9	6
Sales unit package tested as part of a mixed load (in master shipper)	10	6	7
Distribution package (multiple products or sales units) by itself	12	6	5
Distribution package (multiple products or sales units) as part of a unit load (example: pallet load)	6	4	13
Other product/package configuration	4	6	10



- ### Other Results
- How many runs are typically completed to deem your primary package validated?
 - Most common answer=3 (52%)
 - 80% 3 or more
 - If sample size/plan is based on specific reliability, what are the parameters?
 - Confidence
 - 36% do not use
 - Most common answer=95% (36%)
 - Reliability
 - 38% do not use
 - Most common answer=95% (19%)
 - 95 – 99% = 38%.

Other Results

- Among those companies rated as best, there was little reported difference either in techniques used or in performance as compared to the sample as a whole, with the exception that the best showed:
- Much higher development activity (average of 19 vs. 11 per year)
- Somewhat higher recall, 483 and damage rates.

Selected Comments

Also use foam or paperboard inside primary package.

We validate the master shipper or sterilization unit primarily. So, if a product is sterilized in a 10 pack shipper that is the unit we test.

I find that many people don't do there packaging validations. More needs to be done to make manufacturers aware of the standards and other requirements and the need to do all the package validation up front.

Distribution performance testing conducted with packages using minimum seal strength; Distribution performance testing configuration usually consists of multiple sales unit packages in a distribution shipper; process validations to ensure processes are in control and capable; package type used often, but not listed above (14) is flexible formed blister; Materials used often (17) and not listed are PP and nylon;

DOE's, FMEA's, Risk Analysis

Question 30: Single products in their own shipper are transit tested or single unit boxes of the same product are tested in the most likely order quantity and distribution shipper. I have never been able to rationalize the mixing of different products and quantities custom packed in a distribution shipper. I don't know how you can test for any eventuality.

The answers provided will be different within the next 6 months. Corporate SOPs are currently being developed incorporating many of the ASTM F02 standards referenced in an earlier question.

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