



Toy Safety Certification Program

**REVISION FOR TIA BOARD CONSIDERATION
Following Resolution of Public Comments and Subsequent Discussions**

Draft as of April 28, 2008

<u>Contents:</u>	<u>Page</u>
1. Introduction.....	2
2. Scope	3
3. Administration.....	3
4. Referenced Documents	4
5. Terminology	5
6. Program Requirements.....	7
6.1. Hazard Analysis / Risk Assessment.....	7
6.2. Process Control Audits.....	8
6.3. Testing	11
6.4. Certification Program.....	13
Appendices	
1. Federal Requirements	16
2. Program Structure	18
Still in Development:	
3. Factory Audit Checklist	
4. Guidance Document for Factory Audit Checklist	
5. Corrective Action Plan Template	

1. Introduction

In August of 2007, the Toy Industry Association (TIA), as a member of the American National Standards Institute (ANSI), engaged ANSI staff to coordinate a public-private (consumer, government - manufacturer, retailer) partnership to develop technical and international policy guidance regarding conformity assessment solutions for toy safety. It resulted in a guidance document that was published in February 2008 for public comment. More than 120 pages of comments were received representing 36 submittals from a wide range of stakeholders including consumer groups, government, international bodies, manufacturers of varying sizes, retailers, accreditation bodies, testing organizations and auditing companies. The comments were discussed in detail at a two-day meeting in Atlanta, GA attended by key representatives from the toy safety community. This document reflects the outcome of those and subsequent discussions.

The objective of the TIA Toy Safety Certification Program (TSCP) is to develop a sustainable system to enhance both the reality and the public's confidence that toys sold in the U.S. market are safe. The program applies to toys that are produced for sale in the United States and it is designed to assure that toys manufactured in any nation conform to the safety standards used and accepted by the U.S. government and market. Importing companies and domestic manufacturers are responsible for meeting the basic requirements of the program, which are: 1) hazard and risk assessment for toy product design, 2) factory process control audits and 3) production sample testing to validate that the factory is producing toys that meet U.S. safety standards. These three elements will be verified or audited by accredited certification bodies.

Upon successful completion of applicable requirements, the product or packaging may bear a toy safety mark. This mark will be controlled by product certification bodies that are overseen by a single accreditation body (ANSI), authorized by TIA. This mark will help assure consumers, retailers, government agencies and others that the toy bearing the mark will comply with applicable U.S. regulations and consensus safety standards. Use of the mark will be carefully monitored and a website will be developed to allow public identification of certified toys.

While TIA has final responsibility for the administration of the TSCP and is ultimately accountable for its success, this initiative will continue to embrace the input of interested parties. As such, an Oversight Council and a Technical Committee comprised of key stakeholders will be formed to monitor and help improve the penetration and effectiveness of the program going forward.

The TSCP is designed to be an open and global system allowing any qualified organization worldwide to become accredited to be a toy certifying body, a factory process auditor and/or a qualified testing laboratory.

2. Scope

The scope of this initiative covers all toys as defined in ASTM F963 that are intended to be placed into domestic commerce in the United States regardless of the manufacturing location.

All art materials must conform to LHAMA and its regulations 15 USC 1277 and 16 CFR 1500.14(b)(8). Consistent with ASTM F963 requirements, only an art material that is itself or creates an item primarily of play value is covered by this initiative for testing other than LHAMA compliance.

3. Administration

The proposed program will consist of three major components: attestation of product design hazard analysis or risk assessment, factory process control assessment, and production testing (see Program Structure diagrams in Appendix 2). To ensure the credibility of the program, these elements will be verified or audited by providers accredited to acceptable international standards by appropriate accreditation bodies. The specifics are contained in the following sections.

Upon successful completion of the applicable program requirements, the product or its packaging may bear a seal or mark. This mark will help assure consumers, retailers, government agencies and others that 1) the toy product bearing the mark has been designed in accordance with applicable U.S. regulations and consensus safety standards, 2) required samples have been tested from production and 3) the manufacturing facility has been assessed to provide assurance of continued process control.

Accredited certification bodies will control the issuance of the mark itself. TIA has specified that such product certification bodies must be accredited by ANSI, the U.S.-based accreditor that is signatory to the IAF MLA for Guide 65. Other dimensions of accreditation involved in the program (i.e. ISO/IEC 17021 for management systems certification bodies and ISO/IEC 17025 for laboratories) allow for the engagement of other internationally recognized accreditation bodies, as identified in Section 6. TIA will own the mark and will assume overall responsibility for protecting against its counterfeit use.

Fees charged by the various third party service providers will cover costs of the program. Fees paid by the certifiers to the program administrator for licensing the mark will cover costs of overall administration.

Emphasizing the imperative for impartiality, and the necessity to guard against conflicts of interest, it is noted that the ISO/IEC 17011 standards specified in the program for accreditation bodies and the ISO/IEC standards for conformity assessment bodies (laboratories – ISO/IEC 17025, management systems certification bodies – ISO/IEC

17021, and product certification bodies – ISO/IEC Guide 65) all include mandatory requirements enforcing impartiality, objectivity and independence.

Upon TIA Board acceptance of the principles of this proposed program, TIA as sponsor of the program and owner of the toy safety seal will further define how the program will be administered. With inputs from the Oversight Council and the Technical Committee, it will define how progress of the approved program will be reviewed and evaluated, and how desired changes in the program will be implemented.

The Oversight Council will consist of seven members appointed by TIA for three-year terms, including manufacturer, consumer and child/product safety representatives. It will be the duty of the Council to act in an advisory capacity to TIA's Board of Directors regarding the development, implementation, penetration and effectiveness of the program.

Membership on the Technical Committee may include technical experts from the manufacturer, importer, retailer, certifier, auditor, laboratory, factory and consumer communities. It will be the duty of the Committee to act in an advisory capacity to TSCP staff and the Oversight Council regarding technical aspects of the development, implementation, penetration and effectiveness of the program.

4. Referenced Documents

It is expected that the documents listed below will be utilized in the program as outlined in the sections below.

ASTM F963: Standard Consumer Safety Specification for Child Safety
(2007 or most current version)

CPSC Handbook for Manufacturing Safer Consumer Products

CPSC Age Grading Guidelines

ISO/IEC Guide 50: Safety aspects - Guidelines for child safety

ISO/IEC Guide 51: Safety aspects – Guidelines for their inclusion in standards

ISO/IEC Guide 65: General requirements for bodies operating product
certification systems

ISO/IEC 17000: Conformity assessment – Vocabulary and general principles

ISO/IEC 17011: Conformity assessment – General requirements for
accreditation bodies accrediting conformity assessment
bodies

ISO/IEC 17021:	Conformity assessment – General requirements for bodies providing audit and certification of management systems
ISO/IEC 17025:	General requirements for the competence of testing and calibration laboratories
USP 51:	Antimicrobial Effectiveness Test
USP 61:	Microbial Limits Testing
LHAMA/TRA:	Labeling of Hazardous Art Materials Act / Toxicological Risk Assessment

U.S. Federal regulatory requirements for toy safety (see Appendix 1)

5. Terminology

5.1 Definitions

- Accreditation Body* – Authoritative body that performs third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
- Administrator – TIA is the owner and administrator of the program.
- Applicant – The organization that undertakes the certification process for a given toy model is responsible for compliance with the obligations of the certification program and has exclusive rights to the branding of the product associated with the certification. “Applicants” may include, for example, manufacturers, factories, retailers, importers and other stakeholders.
- Certification* – Third-party attestation related to products, processes, systems or persons.
- Conformity Assessment Body* – Body that performs conformity assessment services. (In this document, the terms “audit body”, “certifier”, “certification body”, “laboratory”, and “registrar” are included in this term, depending on the object of their assessment [e.g., system, product, test].) An accreditation body is not a conformity assessment body.
- Factory: A facility that physically produces or assembles toys. Under TSCP, factories will be classified based on factory audit results as Tier 1, Tier 2 or Tier 3.

- Inspection* – Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.
- Manufacturer – Any organization that creates, produces or subcontracts for the production of a toy.
- Surveillance* – Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.
- Testing* – Determination of one or more characteristics of an object of conformity assessment, according to a procedure.
- Toy – TSCP will reference the definition outlined in the current version of ASTM F963 (now, “*any object designed, manufactured, or marketed as a plaything for children under 14 years of age*” with specific exclusions).
- Type Test - a test carried out on samples taken from production for the purpose of determining conformity.

* *consistent with current version of ISO/IEC 17000 vocabulary*

5.2 Acronyms

- ANSI American National Standards Institute
- ASTM ASTM International
- CAP Corrective Action Plan
- CEN European Committee for Standardization
- CFR Code of Federal Regulations
- CPSC U.S. Consumer Product Safety Commission
- IAF International Accreditation Forum
- IEC International Electrotechnical Organization
- ILAC International Laboratory Accreditation Cooperation
- ISO International Organization for Standardization
- MLA Multilateral Agreement

- QMS Quality Management System
- TIA Toy Industry Association
- TRA Toxicological Risk Assessment
- TSCP Toy Safety Certification Program

6. Program Requirements

6.1. Product Hazard Analysis and/or Risk Assessment Documentation

Design hazard analysis and/or risk assessment shall be performed for any products to be certified. This safety assessment should include a review of key elements of ISO/IEC Guide 50 and/or 51, *Handbook for Manufacturing Safer Consumer Products* (U.S. Consumer Product Safety Commission, July 2006) or other similar standards. The design hazard analysis/risk assessment shall be the responsibility of the applicant, who may perform the analysis/assessment in-house (if qualified), or delegate this function to a qualified third party.

Applicants shall ensure that personnel performing the design hazard analysis/risk assessment have appropriate background and experience to complete the analysis, and operate independently from the design function. It is expected that an authorized representative of the applicant will evaluate the adequacy of the hazard analysis/risk assessment process.

6.1.1. Rationale

It is recognized that an effective design hazard analysis and/or risk assessment, with appropriate follow-up action, will help remove reasonably foreseeable hazards prior to manufacture and distribution, help protect children and help reduce the need for recalls. Applicants should accomplish the analysis/assessment as early in the design /manufacturing process as possible.

6.1.2. Documentation and Attestation

Applicants shall document the output of the hazard analysis or risk assessment process that occurred for each unique product. A unique product is one that differs from established toys in design, material or construction such that this difference could influence safety. The hazard analysis or risk assessment may refer to previous similar designs where appropriate.

The results of this analysis will not be submitted as part of the application process. However, attestation by an individual authorized by the applicant that the design hazard analysis and/or risk assessment has been accomplished shall be provided to the certification body at the time of application as identified in

Section 6.4.1. Appropriate attestation shall list the standards and processes used to complete the analysis/assessment.

6.2. Process Control Audits

The purpose of this Process Control Audit system is to evaluate a factory's potential to consistently produce products free of nonconformities by assessing how well its internal systems are planned and designed to be technically sound. Assurance that the products are produced in such a controlled and monitored fashion reduces the risk of manufacturing nonconformities and consequently reduces the need for post-production testing or periodic retesting.

6.2.1. Audit Process

Factory process assessments will be conducted by an independent audit body accredited by an accreditor that is signatory to the IAF MLA for management systems in accordance with ISO/IEC 17021. An audit checklist will be drafted and proposed by the Technical Committee and approved by the Oversight Council.

The auditor will rate each item on the Factory Audit Checklist using one of the following ratings:

RATING	DEFINITION
ACCEPTABLE	Fully meets the requirement.
CONDITIONALLY ACCEPTABLE - REQUIRES IMPROVEMENT	Isolated non-conformance(s) exist that are not evident of a systemic failure and are unlikely to create a product safety defect.
UNACCEPTABLE	Non-conformances exist that demonstrate a systemic failure or that are likely to create a product safety defect.

The auditor will document observations made that led to each rating determination in sufficient detail to permit the factory to both correct any deficiencies as well as maintain acceptable performance.

The factory is responsible for developing and implementing a Corrective Action Plan (CAP) to address root causes of any finding (rating of Requires Improvement or Unacceptable). The CAP should be documented in accordance with the template in Appendix 5 and should identify proposed implementation dates for each CAP item. Follow-up visits will be conducted as necessary to assess successful completion of the CAP and may result in a revised (improved) rating. Corrective action deadlines will be set by the audit company in conjunction with the factory based on the severity of the nonconformities and the amount of time required to implement and verify the effectiveness of the correction. Failure to meet the agreed CAP will result in either a reduction of or failure to advance to a higher Tier level.

Disputes between the factory and the process audit company regarding interpretation of the process control requirements may be referred to the TSCP Executive Director or designee for resolution. In the interim, the decision of the audit company will stand. Disputes regarding administration of the program will also be referred to the TSCP Executive Director or designee.

Unannounced periodic re-audits will be conducted:

- Approximately once a year by factory auditors
- Randomly by certification bodies as part of their internal quality control process
- In the event of reasonably substantiated complaints and/or the need for remediation
- At the discretion of the TSCP Executive Director, such as for a factory that produced nonconforming product subject to a recall.

6.2.2. Technical Requirements

The Factory Audit Checklist will address technical requirements such as:

- Quality Management System
 - Documentation
 - Procedures
 - Records
- Factory Facilities (Good Manufacturing Practices)
 - Calibration, Internal Laboratory
 - Equipment and Maintenance
 - Glass and Sharp Object Control
- Resource Management
 - Organization
 - Training
 - Control of Subcontractors
- Incoming Material Control
 - Supplier Management
 - Material Specifications
 - Incoming Inspection (including assurance that paints and surface coatings meet toxicological requirements)
- Process and Production Control, such as:
 - Plastic Processing
 - Metal Processing
 - Soft Goods Operation
 - Electronics Processing
 - Decorating

- Assembly
 - Final Product Control and Traceability
 - Control and Quarantine of Non-Conforming Materials, Components and Assemblies
- Finished Goods Audits
 - Traceability
 - Manufacturing Date
 - Manufacturing Location

6.2.3. Factory Rating

Upon initial application to the program, factories will be classified as Awaiting Audit. These factories will generally be assigned by the chosen audit company as requiring Testing Frequency C (see table below).

Factories may be considered for an initial Testing Frequency B rating based on submitted evidence of:

- Current ISO 9001 certification or other recognized quality management systems certificate issued by an accredited certification body or a second-party quality system audit
- Product testing history demonstrating that past productions conformed to standards
- No recall history that is related to inadequate process control in the last three years.

The factory must allow an audit to be conducted within six months of the initial application. The accredited audit body, upon completion of the audit, will rate the factory based on the findings. The result will be a rating as a Tier 1, Tier 2, or Tier 3 factory, as defined below. The definition of the testing frequencies assigned to each tier are found in section 6.3.4.

RATING	DEFINITION	TESTING FREQUENCY
TIER 3	A factory that has been audited and found to be unable to demonstrate the presence of an effective basic process control system. In particular, it has serious shortcomings in sections of the checklist having a severity of Critical or Major as defined below.	C

AWAITING AUDIT TESTING FREQUENCY C	A factory that has applied for an audit under the TSCI program, but has not yet been audited. The factory not submitted evidence that would permit testing at Testing Frequency B.	C
TIER 3	A factory that demonstrates an effective basic process control system. It must show full compliance with all Critical requirements of the factory audit checklist and have an acceptable CAP for achieving compliance with all Major requirements or submit other evidence as described earlier in this section.	B
AWAITING AUDIT TESTING FREQUENCY B	A factory that has applied for an audit under the TSCI program, but has not yet been audited. The factory has submitted evidence that would permit testing at Testing Frequency B.	B
TIER 1	A factory that demonstrates full compliance with all Critical and Major requirements of the audit checklist with an acceptable CAP for compliance with any outstanding Minor requirements prior to the next periodic re-audit.	A.
UNAUDITED	A factory that receives an exemption for special circumstances (i.e. not producing toys for the U.S. market on a regular basis). Rating must be approved by the TSCP Executive Director in accordance with guidelines provided by the Technical Committee.	Every shipment or order.

SEVERITY	DEFINITION
CRITICAL	Critical requirements are those that are essential to ensure the continuing production of product that complies with all applicable safety standards.
MAJOR	Major requirements are those that, although not absolutely essential, provide enhanced assurance of the continuing production of product that complies with all applicable safety standards.
MINOR	Minor requirements are those that support the continuing production of compliant product.

6.2.4. Traceability

Traceability of product is required and systems for achieving compliance will be audited as part of the overall factory audit process. Wherever possible, the factory identification and date code will be on the product as well as the retail packaging (either the largest component, on a sewn-in label (soft toys), within a battery compartment or similar location).

If it is not possible or practical to place identification on the product due to size or configuration of use, it must at least be on the retail packaging. Identification is also required on any master carton used for bulk shipping from factory to retailer/brand warehouse.

6.3. Testing

Design of the TSCP program is predicated on the belief that the presence of adequate process controls is the most important element to assuring the continuing production of compliant product. However, the testing component of TSCP provides important evidence in the form of validating production tests as to whether the entire conformity assessment program is effective at a given point in time. Since production testing alone can not provide assurance of the continuing production of product that complies with all applicable safety standards, it is expected that factories will conduct additional levels of testing such as material, component, and in-process testing as a part of their overall process control program. This will be verified as a part of the process control audit.

6.3.1 Technical Requirements

- Applicable US Federal Toy Safety requirements (as referenced in but not limited to Appendix 1)
- ASTM F963 – Standard Consumer Safety Specification for Toy Safety (most recent version). The TSCP implementation date for subsequent versions will be determined by the TSCP Executive Director in accordance with the Technical Committee.

6.3.2 Preproduction and Production Sample Testing

All tests as prescribed in this program and pertaining to Section 6.3.1 shall be performed by laboratories accredited to ISO/IEC 17025 by ILAC-recognized accreditation bodies or, in the case of art materials, shall be acceptable to a board-certified toxicologist as defined in 16 CFR 1500.14(b)(8).

Compliance with the following requirements that are established industry practice may be demonstrated by means including preproduction testing (e.g. of materials or samples) or testing of production samples:

- Microbial USP 61 (ASTM F963 8.4.1; test results within standard industry practice of 1 year)

- Antimicrobial USP 51 (ASTM F963 8.4.2; test results within standard industry practice of 5 years)
- LHAMA/TRA (test results within standard industry practice of 5 years)

For USP 51, USP 61 and LHAMA/TRA tests, component (e.g., a pen or marker) tests are acceptable with reference to current test report from an accredited test laboratory or certified toxicologist and when traceability is evident.

6.3.3 Sample Size for Production Testing

The following guidelines, taken in part from CPSC test procedures, are recommended for sampling products:

- Toys intended for use by children under 3 years old, use 18 randomly selected samples (under-age-3 items have more tests specified in ASTM F963 than over-age-3 items)
- Toys intended for use by children older than 3 years old, use 12 randomly selected samples
- In cases where 12 or 18 samples are not sufficient to conduct the range of applicable tests, additional samples will be tested
- Minimum sample requirements for heavy element testing will be conducted as described in ASTM F963
- The samples shall be obtained from and shall be representative of actual production, with date codes recorded on the test report.

When production size is limited (less than 1,000 units a year), the applicant and certification body shall reach an agreement on the appropriate sample size for production testing.

6.3.4 Test Frequency for Each Unique Product

TEST FREQUENCY CODE	FREQUENCY
A	Minimal testing annually or at least every million units, not to exceed four times per year
B	Minimum testing semiannually or at least every 500,000 units, not to exceed four times per year
C	Minimum testing quarterly or every 150,000 units, not to exceed six times per year
Unaudited	Every shipment or order

The same products made at different locations are treated as separate products (types).

Consolidated testing is acceptable for some products because of their similar design and construction. Products that have the same “base

design” and differ only with respect to decoration can be grouped into a consolidated batch and considered the same for purposes of mechanical testing. Products manufactured using the same chemical compounds can be considered the same for purposes of chemical testing.

All test results will be reported promptly to the factory, the applicant, and the certification body.

6.4. Certification Program

6.4.1 Administration of Certification Program

- The structure of the program is outlined in Appendix 2
- Three documents are required for issuance of certification:
 - 1) Passing test report for production samples as described in Section 6.3
 - 2) Factory rating as described in Section 6.2.3
 - 3) Attestation that a design hazard analysis/risk assessment has been performed in accordance with Section 6.1.2.
- Each of these must be provided to the certification body and remain current as described in the sections above.
- In the event that the certification body becomes aware of a non-conformance through a failing production test, lack of a factory audit, or a reasonably substantiated complaint, a notice of non-conformance will be issued to the applicant. If the non-conformance cannot be resolved, including disposition of product and notification of relevant parties, within a reasonable period of time, the certification body will withdraw certification of the product.

6.4.2 Certifiers

- Certification organizations shall be accredited by ANSI, the U.S.-based accreditor that is signatory to the IAF/MLA for product certification.
- Requirements for certification organization accreditation are ISO/IEC Guide 65 plus minimum technical and program requirements specified in this document and those developed during the final development phase of the TSCP program.

6.4.3 Attestation of Conformity

- Certified products may bear a certification mark or seal on the packaging and or product.

- Each certifier shall maintain an up-to-date list of currently certified products that is available through the TSCP website.
- Certification status will be listed and publicly available on the TSCP website.

6.4.4 Product Revisions and Modifications

Renewal of certification is required with any design or process change that could affect the safety of the product.

APPENDIX 1: U.S. Federal Requirements

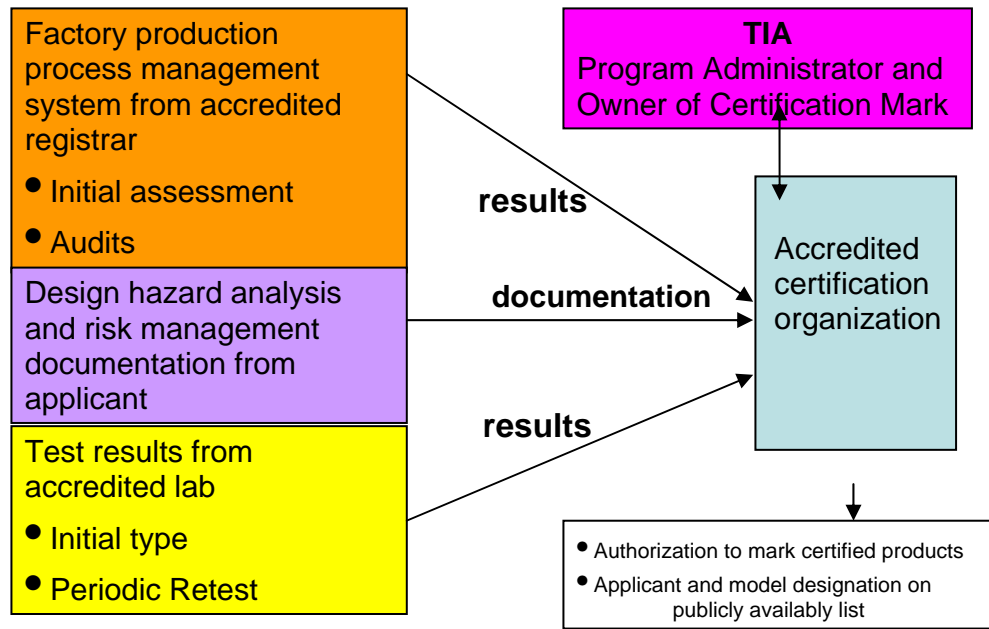
(The following requirements can be found in the U.S. Code of Federal Regulations – CFR.)

15 CFR Part 1150	Marking of Toys, Look-Alike and Imitation Firearms
16 CFR Part 1303	Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead Containing Paint
16 CFR Part 1500	Hazardous Substances Act Regulations, including the following sections: <ul style="list-style-type: none">▪ 1500.3 (b) (15) (i) Definition of "banned hazardous substance"▪ 1500.3 (c) (6) (vi) Definition of "flammable solid"▪ 1500.14(b) (8) Labeling of hazardous art materials, evaluated in conformance with ASTM D4236▪ 1500.18 Banned toys and other banned articles intended for use by children▪ 1500.19 Misbranded toys and other articles intended for use by children▪ 1500.44 Method for determining extremely flammable and flammable solids▪ 1500.47 Method for determining the sound pressure level produced by toy caps▪ 1500.48 Technical requirements for determining a sharp point in toys and other articles intended for use by children under 8 years of age▪ 1500.49 Technical requirements for determining a sharp metal or glass edge in toys and other articles intended for use by children under 8 years of age▪ 1500.50-53 Test method for simulating use and abuse of toys and other articles intended for use by children▪ 1500.83 Exemptions for small packages, minor hazards, and special circumstances▪ 1500.85 Exemptions from classification as banned hazardous substances▪ 1500.86 Exemptions from classification as a banned toy or other banned article for use by children

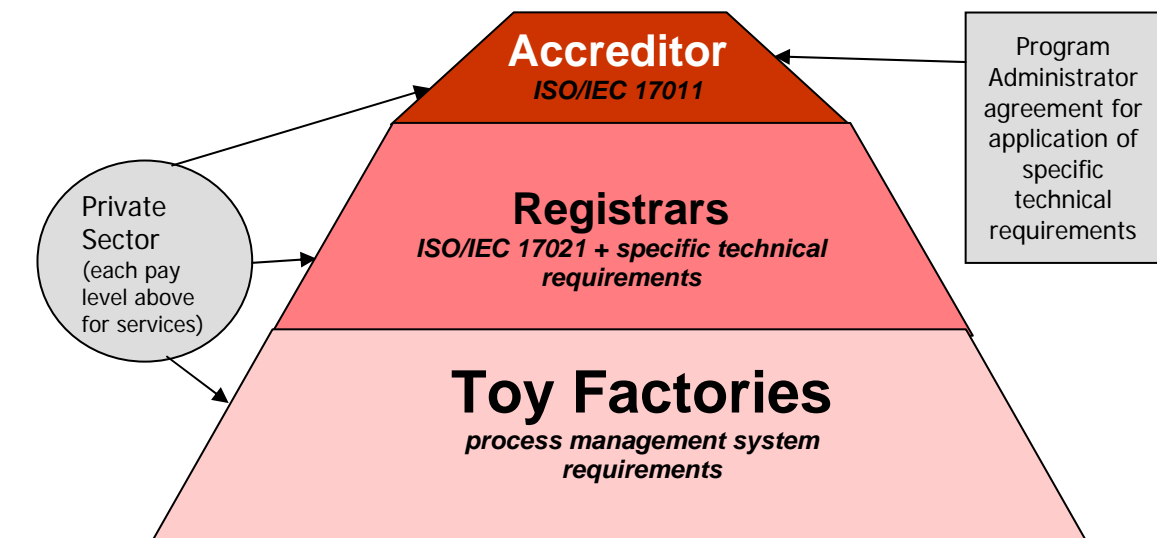
16 CFR Part 1501	Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts
16 CFR Part 1505	Requirements for Electrically Operated Toys or Other Electrically Operated Articles Intended for Use by Children
16 CFR Part 1510	Requirements for Rattles
16 CFR Part 1511	Requirements for Pacifiers
16 CFR Part 1610	Standard for Flammability of Clothing Textiles
21 CFR Part 110	Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding Human Food
21 CFR Part 170-189	Food for Human Consumption
21 CFR Part 700-740	Requirements for Specific Cosmetic Products

NOTE: If, in the opinion of a toxicologist certified by the American Board of Toxicology or as defined in 16 CFR 1500.14 (b)(8), a toxicological risk assessment is satisfactory to determine compliance with those CFR regulations referencing testing procedures involving animals, such assessment will be considered sufficient evidence of compliance for the purposes of this program.

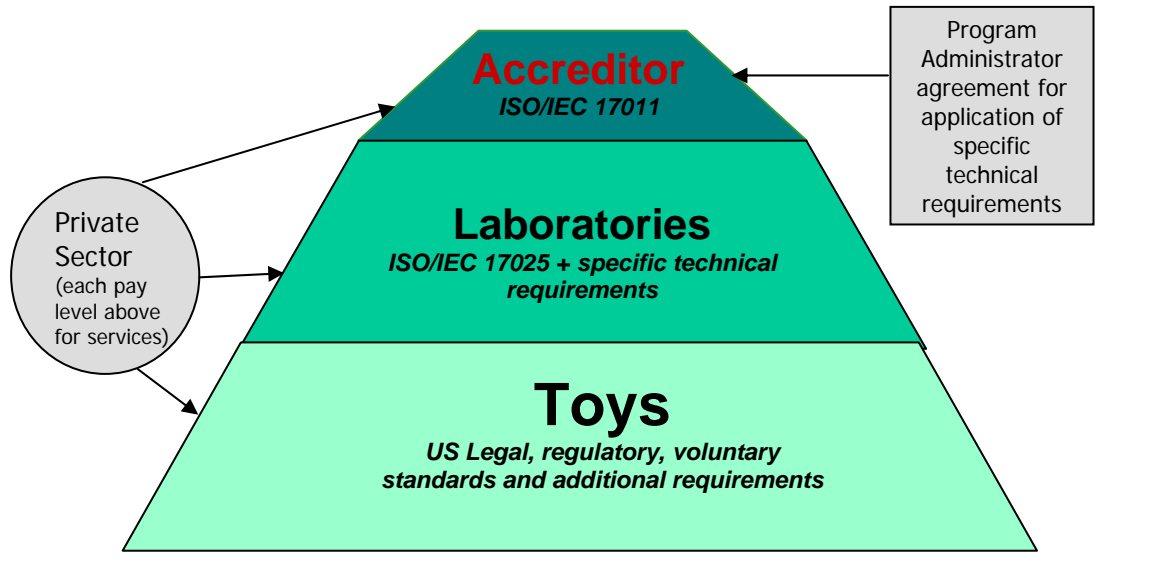
Toy Safety Certification



Toy Certification Program Accreditation Model for Registrars



Toy Certification Program Accreditation Model for Laboratories



Toy Certification Program Accreditation Model for Certifiers

