



TOY SAFETY COORDINATION INITIATIVE

DRAFT PROGRAM RECOMMENDATIONS

Publication

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ANSI
American National Standards Institute

Toy Industry Association, Inc.
Leading the Growth and Health of the Toy Industry

Toy Safety Coordination Initiative

Program Recommendations

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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 with regard to conformity assessment solutions for toy safety. This document describes that guidance. The objective of this Toy Safety Coordination Initiative (TSCI) 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 by 1) assuring that they meet all U.S. Federal and consensus toy safety requirements; 2) incorporating Designer/Manufacturer product hazard and risk assessment documentation for toys; and 3) implementing this system in the most efficient way possible, taking into account the impacts on product innovation, time-to-market, and small businesses.

This initiative is a collaborative effort between TIA, ANSI and their mutual stakeholders including representatives from government agencies and consumer organizations. Upon acceptance of this recommendation by the TIA Board of Directors, efforts will continue towards a detailed plan for implementation. TIA has final responsibility for the administration of this program and is ultimately accountable for its success.

2. Scope

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

3. Administration

The proposed program will consist of three major components: Manufacturer/Designer hazard analysis or risk assessment documentation, 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 by appropriate accreditation bodies to accepted international standards. The specifics are contained in the following sections.

Upon successful completion of the applicable program requirements, the product or packaging would bear a seal or mark. Through retailer and consumer education, the presence of the mark will enhance confidence that any toy that bears it complies with all applicable regulations and consensus safety standards for the U.S. market. The issuance of the mark itself will be controlled by an accredited certification body. The certification body(s) must be accredited by a U.S. based accreditor that is signatory to IAF MLA for Guide 65 in accordance with ISO/IEC 17011.

Costs of the program will be covered by fees charged by the various third party service providers. Costs of administration will be covered by fees paid by the certifier to the program administrator for licensing the mark. While there has been consideration given to some sort of self-certification approach, it is the opinion of the steering committee that

such an approach would not provide the level of confidence required by U.S. regulators and consumers.

Upon acceptance of the principles of the proposed program, TIA will identify how such a program will be administered – especially the ownership and use of any mark. As the initiator of this effort, TIA will play a major role in providing administration, leading the establishment or identification of an organization to administer the program, defining how the progress of the program (as approved and implemented) will be reviewed and evaluated, and how desired changes in the program will be implemented.

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*	
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

- 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 manufacturers, factories, retailers or other stakeholders.

- Certification – The TSCI utilizes the definition outlined in the current version of the ISO/IEC 17000 standard (now, "*third-party attestation related to products, processes, systems or persons*").

- Factory: A facility that physically produces or assembles toys or toy subassemblies. Under the TSCI, factories will be classified based on factory audit results, as "Tier 1, 2 or 3".

- Inspection – The TSCI utilizes the definition outlined in the current version of the ISO/IEC 17000 standard (now, "*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 manufactures wholly or partially a toy.

- Surveillance – The TSCI utilizes the definition outlined in the current version of the ISO/IEC 17000 standard (now, "*systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity*").

- Testing – The TSCI utilizes the definition outlined in the current version of the ISO/IEC 17000 standard (now, "*determination of one or more characteristics of an object of conformity assessment, according to a procedure*").

- Toy – The TSCI will reference the definition outlined in the current version of the ASTM F963 standard (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

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
- TSCI Toy Safety Coordination Initiative

6. Program Requirements

6.1. Manufacturer/Designer product hazard analysis and/or risk assessment documentation

Design hazard analysis and/or risk assessment shall be performed. 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, or delegate this function to a third party.

Applicants are encouraged to perform the analysis/assessment as early in the design/manufacturing process as possible, and are encouraged to ensure that personnel performing the design hazard analysis/risk assessment have the necessary skills to complete the analysis.

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.

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. This documentation will not be submitted as part of the application process.

Attestation 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/processes used to complete the analysis/assessment.

6.2. Process Control Audits

While testing (described in Section 6.3) provides post-production evidence of product conformity, confidence in compliance to standards and regulations can best and most consistently be achieved when there is a competent system of production and quality controls that ensure that inherent process variabilities and changes to the manufacturing process do not negatively affect product conformance. Good manufacturing process controls can prevent nonconforming products from being produced. This helps to ensure that they are corrected in the most efficient manner possible before they reach the marketplace, rather than being identified after the fact in the post-production testing process.

The purpose of this Process Control Audit system is to evaluate a factory's ability to consistently produce products without defects based on a planned and technically

sound system. Assurance that the products are produced in such a controlled and monitored fashion reduces the risk of manufacturing defects and consequently reduces the need for post-production testing or periodic retesting.

6.2.1. Audit Process

Factory quality process assessments will be conducted by an independent audit body accredited by a U.S.-based accreditor that is signatory to the IAF MLA for management systems in accordance with ISO/IEC 17021. An audit checklist will be developed and approved by a technical committee appointed by TIA. Until this is completed, the checklist in Appendix 3 or another similar checklist may be used. The technical committee will consist of representatives from third party audit firms, manufacturers and other stakeholders as appropriate.

For each item on the Factory Audit Checklist, the auditor will rate the factory's performance as:

- Acceptable;
- Requires Improvement; or
- Unacceptable

The auditor will document sufficient details of the observations made that led to the rating determination.

The factory is responsible for developing and implementing a Corrective Action Plan (CAP) to address root causes of any negative findings (i.e. 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 to assess the success of the CAP and may result in a revised (improved) rating

Unannounced periodic (approximately annual) re-audits will be conducted.

6.2.2. Technical Requirements

The consensus audit standard 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 sub-contractors

- 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 defective materials, components and assemblies

- Finished Goods Audits

- Traceability
  - Manufacturing Date
  - Manufacturing Location

6.2.3. Factory Rating

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 3, Tier 2, or Tier 1 factory.

- Tier 3 factories lack the basic elements of process control. They will require the highest frequency of testing in an accredited laboratory to assure continuing product compliance.

- Tier 2 factories must demonstrate an effective basic process control system. They will require a reduced frequency of testing in an accredited laboratory to assure continuing product compliance. They must have show full compliance with all Critical requirements of the standard and have an acceptable CAP for achieving compliance with all Major requirements prior to the next scheduled re-audit.

- Tier 1 factories will demonstrate an advanced process control system. They will require testing in an accredited laboratory at the lowest frequency to assure continuing product compliance. They must show

full compliance with all Critical and Major requirements with an acceptable CAP for compliance with any outstanding Minor requirements prior to the next scheduled re-audit.

- Upon initial application to the program, factories will be assigned by the administrator as Tier 3 (or Tier 2, based on submitted evidence of current ISO 9001 certification, or other recognized quality management systems certificate, issued by a certification body that has been accredited by a U.S.–based ISO/IEC 17011 accreditor that is signatory to IAF MLA, equivalent third party audits, and/or product testing history).

- Factories will be required to undergo an audit within 12 months of their initial application to continue to use the mark. A percentage of factories may be subject to an unannounced validation audit as part of an internal quality control process. Unannounced audits will also take place in the event of reasonably substantiated complaints.

6.2.4. Traceability

Traceability of product will be required and compliance will be audited as part of the overall 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 to place identification on the product due to size or configuration of use then it will be on the retail packaging only. Identification is also required on any master carton used for bulk shipping from factory to retailer/Brand warehouse.

6.3. Testing and Reporting

6.3.1 Technical Requirements

- Applicable US Federal Toy Safety requirements (See Appendix 1)
- ASTM F963 – Standard Consumer Safety Specification for Toy Safety (most recent version)

6.3.2 Testing

All tests shall be performed by laboratories accredited to ISO/IEC 17025 by ILAC-recognized accreditation bodies.

Preproduction testing is acceptable to demonstrate compliance with the following requirements:

- Microbial USP 61 (ASTM F963 8.4.1; test results within 1 year)
- Antimicrobial USP 51 (ASTM F963 8.4.2; test results within 5 years)

- LHAMA/TRA (test results within 5 years)
- Material or compound identification testing (also referred to as “fingerprint testing”) may be used to assure consistency of formulation according to the test frequency plan

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

6.3.3 Sample Size

The following guidelines are recommended for sampling products:

- Toys intended for use by children under 3 years-old use 18 randomly selected pieces
- Toys intended for use by children older than 3 years-old use 12 randomly selected pieces *(Rationale: Under age 3 items have more tests specified in ASTM F963)*
- In cases where the number of samples is not sufficient to conduct the range of applicable tests, additional samples will be tested.
- The samples shall be obtained from and shall be representative of actual production with date codes which will be recorded on the test report.

6.3.4. Tier Structure

- Tier Structure (all factories start out as Tier 3)
    - Tier 1 (lowest frequency)
        - Minimum testing annually or at least every million units, not to exceed four times per year.
    - Tier 2 (intermediate frequency)
        - Minimum testing semiannually or at least every 500K units, not to exceed four times per year.
    - Tier 3 (maximum frequency)
        - Minimum quarterly or every 150k units, not to exceed six times per year.
- The same or similar products made at different locations are treated as separate products (types).

6.3.5. Product Surveillance

- Factory audits as described in Section 6.2.1
- Periodic retesting as described in 6.3.2

6.4. Certification Program

6.4.1 Administration of Certification Program

- Program will be administered by TIA and/or designee.

- The proposed structure of the program is outlined in Appendix 2
- Requirements for Certification
    - Three documents are required for issuance of certification:
        1) Passing Test report
        2) Passing Factory audit report
        3) Attestation that a design hazard analysis/risk assessment has been performed in accordance with Section 6.1.2 above. This attestation need not be submitted until the date upon which the product enters into production.
    - Each of these documents must be provided to the certification body and be current as described in the Testing and Reporting and Audit sections above.

6.4.2 Certifiers

- Certification organizations shall be accredited by U.S.-based accreditor that is signatory to IAF MLA for ISO/IEC Guide 65 in accordance with ISO/IEC 17011.
- Certification organization accreditation requirements - ISO/IEC Guide 65, plus technical and program minimum requirements specified in this document.

6.4.3 Attestation of Conformity

- Certified products will bear a certification mark or seal.
- The mark or seal will identify the certification program and uniquely identify the certifier of marked toys as well as the appropriate age grading of the toy.
- Each certifier shall maintain an up-to-date list of currently certified products that is publicly available on the internet.

6.4.4 Business Model

- Manufacturer/Supplier will pay certifiers, audit bodies and laboratories for services.
- Certifiers, audit bodies and laboratories will pay for their own accreditation services (as well as fees to the program administrator for mark license).
- Impartiality of inspectors and auditors shall be in accordance with ISO/IEC 17011, ISO/IEC 17021, ISO/IEC 17025 and ISO/IEC Guide 65.

6.4.5 Demand Drivers for certification mark or seal

- Retailers will require certification for purchase of toys to sell to consumers.
- Consumers will use certification marks to make informed decisions.
- Enhanced regulatory confidence in breadth of compliance.

- CPSC staff participation in the development of the TSCI program recommendation.
- Reduced redundancy of testing.

6.4.6 Product Revisions and Modifications

- Renewal of certification is required with any design or process change that could affect the safety of the product (i.e., material change, raw material supplier change, new factory, etc.)

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:

- 1500.3 (c) (6) (vi) Definition of “flammable solid”
- 1500.14(b) (8) Labeling of hazardous art materials
- 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

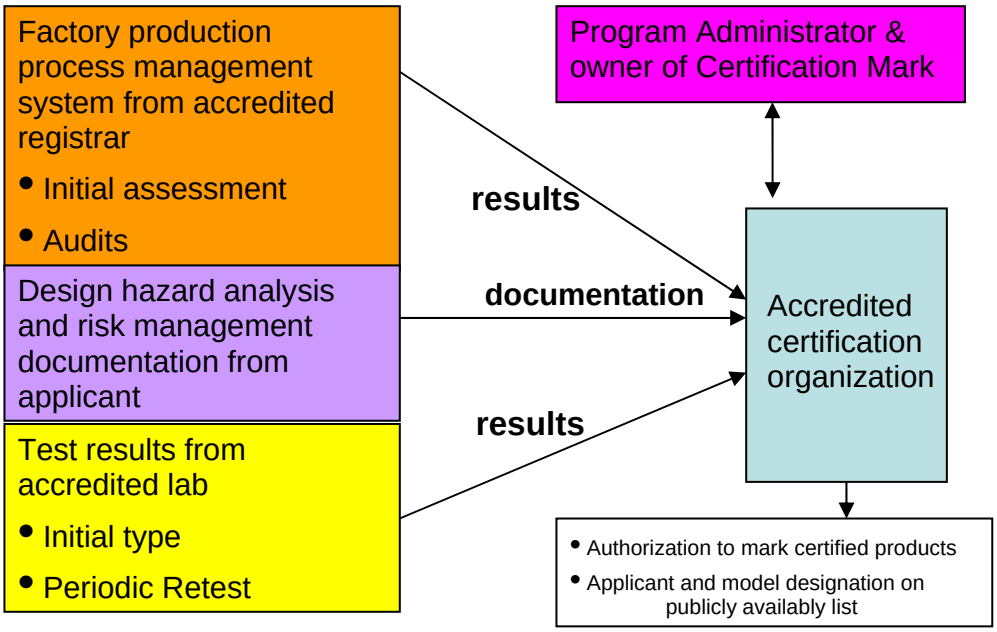
16 CFR Part 1501	Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts
16 CFR Part 1505	Requirements for Electrically Operated Toys or Other Electrically Operated Articles Intended 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

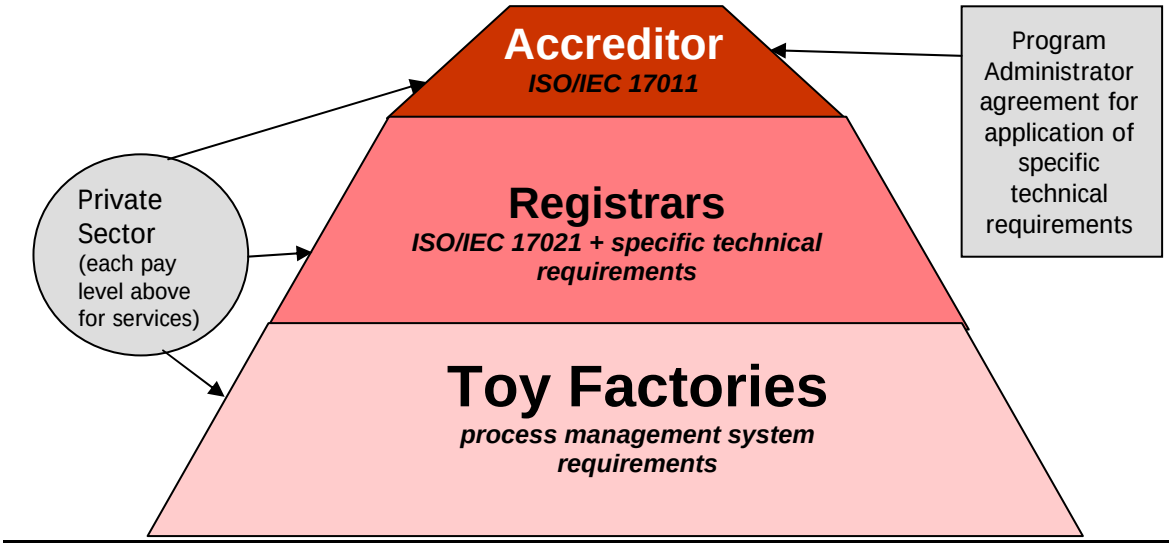
NOTE: If, in the opinion of a toxicologist certified by the American Board of Toxicology, a toxicological risk assessment is satisfactory to determine compliance with those CFR regulations referencing testing procedures involving animals, such assessment will be considered sufficient evidence of compliance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

APPENDIX 2: Program Structure

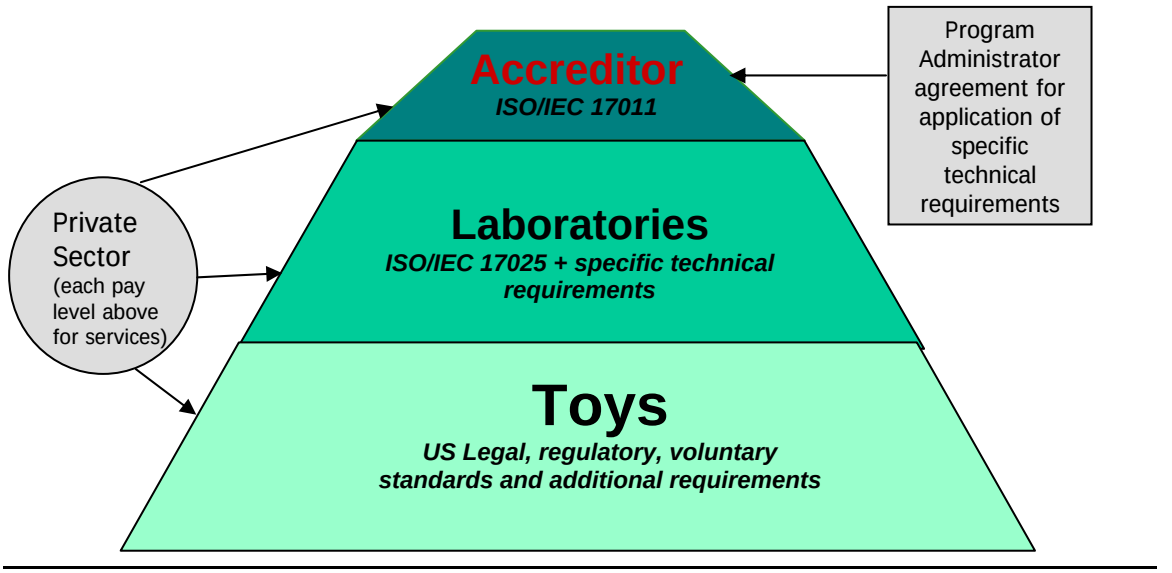
Toy Safety Certification



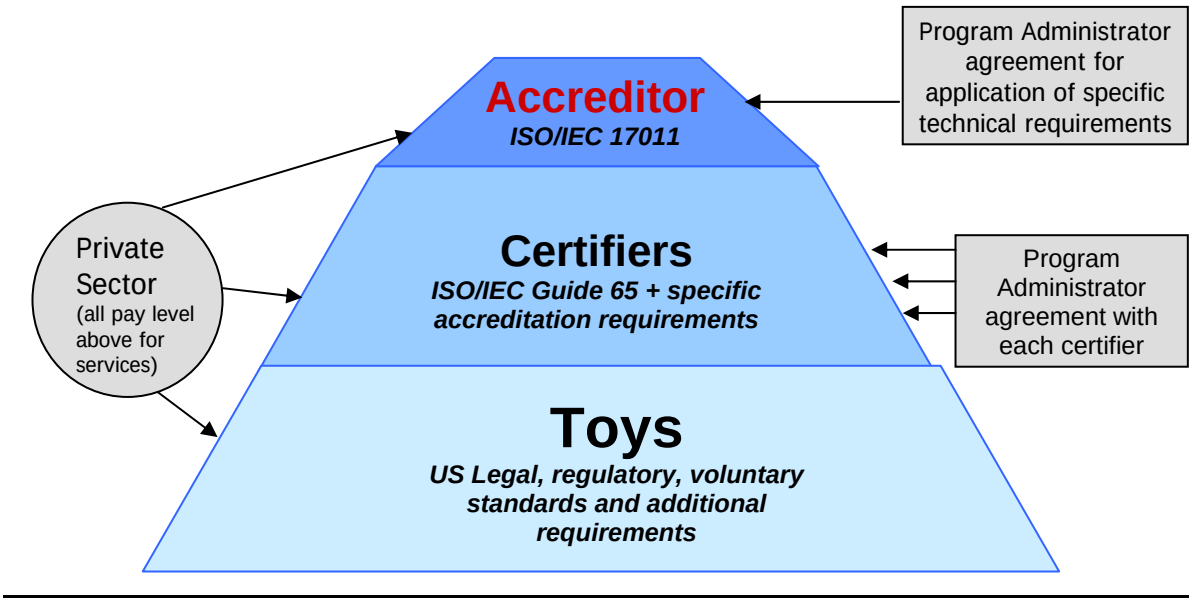
Toy Certification Program Accreditation model for registrars



Toy Certification Program Accreditation model for laboratories



Toy Certification Program Accreditation model for certifiers



Appendix 3: Initial Draft/Sample Factory Audit Checklist

Revision Date: 17 Jan 2008 - Provided as an example only

Clause #	Clause Requirements	Question Rating	Degree of Compliance (A = acceptable, NI = need improvement, U = unacceptable)				Comments
1	**QUALITY MANAGEMENT SYSTEMS (QMS)**						
	The factory shall be able to demonstrate effective control of product and operations are undertaken. The factory shall define and implement Quality Management System which is appropriate to meet all customer safety, legal, and quality requirements.						
1.1	**Organizational Structure, Responsibility and Management Authority**						
	The factory shall have an documented organizational structure, which clearly defines job function, responsibility, authority, and reporting relationships of those staff whose activities affect product safety, legal and quality requirements to meet their customer expectations.						
1.1.1	**The factory shall define and communicate the levels of responsibility and authority of staff that may affect product safety, legality and quality.**	**Critical**	**A**	**NI**	**U**	**N/A**	
1.2	**Procedures**						
	The factory shall define and implement procedures, instructions, forms and reference documents to effectively manage all processes that may affect product safety, legality, and quality.						
1.2.1	**The factory shall define procedures, instructions, and reference documents in written to effectively manage all processes that may affect product safety, legality, and quality.**	**Major**	**A**	**NI**	**U**	**N/A**	
1.2.2	**The factory shall ensure all written procedures, instructions, and reference documents are effectively implemented at all processes that may affect product safety, legality, and quality.**	**Minor**	**A**	**NI**	**U**	**N/A**	

1.3	**Document Control**							
	The factory shall ensure that all documents, records and data required for management of product safety, legality and quality are established, implemented, maintained and controlled to ensure all users have the current revision of procedures, work instructions and records needed to meet customer requirements. Authority for establishing, changing, controlling, and retaining documents shall be defined.							
	1.3.1	**The factory shall be aware of and have access to current documents, complete specifications provided by customer, and legislation relating to the safety and legality of the product, during its product design or development stage, for the countries in which they are to be manufactured and sold.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	1.3.2	**The factory shall define and implement proper documentation for control of formulas, specifications, procedures and work instructions. The authority and procedure for establishing, changing, controlling documents shall be defined.**	**Major**	**A**	**NI**	**U**	**N/A**	
	1.3.3	**All relevant safety, legal, and quality compliance documentation shall be retained in good condition for the time specified by retailers, brands or other related parties and regulatory bodies and shall be at the disposal of regulatory authorities, retailers, brands or end users upon request.**	**Major**	**A**	**NI**	**U**	**N/A**	

1.4	**Corrective Action**							
	The factory shall define and implement procedures to identify and investigate the cause(s) of internal or external non-conformity against standards, specifications and procedures, which are critical to product safety, legality and quality. Effective corrective action shall be taken to prevent reoccurrence.							
	1.4.1	**The factory shall have a documented system for identifying and managing product complaints and/or non-conformities, and their corrective actions.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	1.4.2	**Records shall be maintained when the factory has taken actions to eliminate the root cause of complaints and/or non-conformities against operation procedures in order to prevent recurrences.**	**Major**	**A**	**NI**	**U**	**N/A**	

2	**FACTORY FACILITIES (GOOD MANUFACTURING PRACTICE)**							
	The factory shall apply Good Manufacturing Practice throughout the factory, so as to prevent contamination and enable the production of safe, legal, and quality products.							
2.1	**Building Exterior And Interior**							
	All facilities and grounds within the site shall be suitably constructed and maintained to meet safety, legal, and quality requirements.							
2.1.1	**Building exterior and interior shall be maintained in good condition to prevent deterioration of or damage to materials and products.**	**Major**	**A**	**NI**	**U**	**N/A**		
2.2	**Layout/Product Flow**							
	Premises and plant shall be designed, constructed and maintained to prevent non-conforming product.							
2.2.1	**The process flow from receiving to shipping shall be designed to prevent non-conforming product or contamination.**	**Major**	**A**	**NI**	**U**	**N/A**		
2.3	**Equipment and Maintenance**							
	Equipment shall be suitably designed for the intended purpose and shall be used and maintained to prevent non-conforming product.							
2.3.1	**Equipment and production machinery shall be properly designed, constructed, and installed to prevent non-conforming product during all production capacities.**	**Minor**	**A**	**NI**	**U**	**N/A**		
2.3.2	**The factory shall define and conduct preventive maintenance programs to ensure all equipment and production machinery are adequately maintained to operate safely and efficiently.**	**Minor**	**A**	**NI**	**U**	**N/A**		
2.3.3	**The factory shall ensure that the safety of products is not affected during maintenance or housekeeping operations.**	**Major**	**A**	**NI**	**U**	**N/A**		

2.4	**Pest Control**							
	The factory shall be responsible for prevention of pest infestation affecting product safety, legality, and quality.							
	2.4.1	**The factory shall either contract the services of a competent pest control organization, or shall have trained personnel, for the regular inspection and treatment of premises to deter and eradicate infestation.**	**Major**	**A**	**NI**	**U**	**N/A**	
	2.4.2	**No evidence shall be present of pest activity that could compromise product safety, legality, and quality.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	2.4.3	**Pest activity report with corrective actions shall be completed at defined intervals and satisfactorily verified.**	**Minor**	**A**	**NI**	**U**	**N/A**	

2.5	**Chemical Control**							
	The factory shall define and implement procedures to prevent chemical contamination throughout the manufacturing and storage of products and materials.							
2.5.1	**All Material Safety Data Sheets (MSDS) or equivalent documents shall be on file and up to date.**	**Major**	**A**	**NI**	**U**	**N/A**		
2.5.2	**All chemical types shall be handled by authorized / trained staff.**	**Minor**	**A**	**NI**	**U**	**N/A**		
2.5.3	**All chemical types are appropriately labeled and segregated during storage and separated from raw materials and finished products by a physical barrier.**	**Critical**	**A**	**NI**	**U**	**N/A**		
2.6	**Segregation and Stock Rotation**							
	Procedures shall be defined and implemented to prevent the cross contamination of raw materials, packaging and finished products.							
2.6.1	**Procedures shall be in place to prevent the contamination of raw materials, packaging and finished products.**	**Major**	**A**	**NI**	**U**	**N/A**		
2.6.2	**Procedures shall be in place to assure materials and products are used prior to end of shelf life (as applicable) where safety, legality, or quality will be affected.**	**Major**	**A**	**NI**	**U**	**N/A**		

2.7	**Foreign Body Contamination**							
	The factory shall define and implement procedures to detect and prevent metal, glass or other foreign body product contamination.							
	2.7.1	**The factory shall define and implement procedures for the control and monitoring of sharp items such as blades and needles, which shall be collected and documented before replacements are issued.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	2.7.2	**The factory shall establish and implement procedures for calibration, operation, and routine monitoring when a metal or foreign body detector is used.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	2.7.3	**The factory shall establish reporting procedures and implement remedial action, in the event of the monitoring and testing procedure identifying any failure of the metal or foreign body detector. These will include the recall, quarantining and re-inspection of all product produced since the last acceptance test of the metal or other foreign body detector.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	2.7.4	**Records of metal or foreign body detection shall be maintained so that the product is fully identified and traceable.**	**Major**	**A**	**NI**	**U**	**N/A**	
	2.7.5	**The factory shall have a policy preventing the wearing of potentially contaminating articles such as jewelry, earrings, etc.**	**Major**	**A**	**NI**	**U**	**N/A**	

2.8	**Control of Non-Conforming Materials**							
	The factory shall define and implement procedures to ensure all non-conforming materials, including raw materials, work-in-process, and finished goods are clearly identified, segregated and dispositioned.							
	2.8.1	**The process for segregation and disposition of non-conforming materials shall be defined, including the authority levels for segregation and disposition (rework, scrap, and waiver).**	**Major**	**A**	**NI**	**U**	**N/A**	
	2.8.2	**All non-conforming materials shall be clearly identified and segregated until disposition.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	2.8.3	**All non-conforming product shall be handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.**	**Minor**	**A**	**NI**	**U**	**N/A**	
	2.8.4	**The factory shall have a procedure for disposing of nonconforming product with toy industry safety mark on it or it's packaging.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	2.8.5	**Effective corrective actions shall be implemented to avoid recurrence of non-conformance and adequate documentation kept of the action taken.**	**Minor**	**A**	**NI**	**U**	**N/A**	

2.9	**Calibration and Control of Measuring and Monitoring Devices**							
	The factory shall define and implement procedures to calibrate and maintain measuring equipment used to monitor critical control points, for product safety, legality, and quality. Should any measuring or monitoring equipment be found out of calibration, all product produced from the time of last acceptable calibration date must be reviewed and any corrective action shall be taken as needed.							
	2.9.1	**The factory shall identify all measuring equipment used to monitor critical/major elements of product safety, legality, and quality.**	**Major**	**A**	**NI**	**U**	**N/A**	
	2.9.2	**Measuring and monitoring equipment shall be routinely calibrated to recognized national standards.**	**Major**	**A**	**NI**	**U**	**N/A**	
	2.9.3	**Records of equipment calibration and re-calibration shall be maintained.**	**Minor**	**A**	**NI**	**U**	**N/A**	
	2.9.4	**Measuring and monitoring equipment found to be out of calibration shall be immediately re-calibrated or replaced and records of event shall be documented.**	**Major**	**A**	**NI**	**U**	**N/A**	
	2.9.5	**Records shall be maintained when the factory has taken appropriate action (product accounted for) for any product affected from out of calibration measuring equipment.**	**Critical**	**A**	**NI**	**U**	**N/A**	

3	**RESOURCE MANAGEMENT**							
	The factory shall determine and provide sufficient resources to ensure the manufacturing of safety, legal and quality product and meet customer specifications and requirements.							
3.1	**Training**							
	The factory shall define and implement procedures to assure that all employees are adequately trained, instructed and supervised commensurate with their job activity related to product safety, legality and quality.							
3.1.1	**All personnel shall be appropriately trained prior to commencing work and adequately supervised throughout the working period.**	**Critical**	**A**	**NI**	**U**	**N/A**		
3.1.2	**The factory shall maintain training records for employees whose job activities are related to product safety, legality and quality.**	**Major**	**A**	**NI**	**U**	**N/A**		

4	**INCOMING MATERIAL CONTROL**							
	The factory shall define and implement effective incoming material control procedures to ensure all materials related to safety, legal and quality meet product and customer specifications and requirements.							
4.1	**Supplier Approval and Performance Monitoring**							
	The factory shall define and implement procedures for approval and the monitoring of its suppliers to meet all quality, safety, and legal requirements.							
4.1.1	**The factory shall define and implement procedures for supplier and sub-contractor approval and on-going monitoring of performance. Criteria of the approval process and standards of performance shall be defined.**	**Major**	**A**	**NI**	**U**	**N/A**		
4.2	**Incoming Raw Materials Control**							
	The factory shall define and implement procedures to control incoming raw materials to assure only conforming materials are used in the production of products.							
4.2.1	**Procedures shall be defined and implemented for the inspection and approval of incoming raw material to assure conformance to agreed specifications and requirements.**	**Critical**	**A**	**NI**	**U**	**N/A**		
4.2.2	**The factory shall maintain records showing proof that all materials such as paints, coatings and non-paint components (including non fabric trims, accessories, hardware and labels, etc.) are tested for lead and heavy metals content and complied with the safety and legality requirements where the products are sold, as applicable?**	**Critical**	**A**	**NI**	**U**	**N/A**		
4.2.3	**Parts shall be inspected against specified product quality requirements (i.e. defects, deformation, color, date code, size and dimensions, etc.).**	**Major**	**A**	**NI**	**U**	**N/A**		
4.2.4	**Specified sampling plans and levels of acceptance/rejection criteria for incoming raw materials shall be defined.**	**Major**	**A**	**NI**	**U**	**N/A**		

5	**PROCESS AND PRODUCT CONTROL**							
	The factory shall define and implement procedures to effectively manage product and processes during production. Where control of the raw materials, intermediate or finished product, processes and/or environment is required to ensure product safety, legality and quality, there shall be adequate control, monitoring and record keeping. Where parameters such as raw material quality, in process control and final inspection which govern product safety, quality and legality these shall be controlled monitored and recorded.							
5.1	**Work-in-Process Product Analysis / Testing**							
	The factory shall define and implement procedures to conduct or subcontract analyses or testing, critical to confirm product safety, legality and quality, using appropriate procedures, facilities and standards, for those in-process semi-finished products.							
5.1.1	**The factory shall establish procedures to conduct or subcontract analyses or testing, critical to confirm product safety, legality and quality.**	**Major**	**A**	**NI**	**U**	**N/A**		
5.1.2	**Conformance to specification/formulation shall be measured at the sample size, frequency and defined methods to assure product safety, legal and quality requirements are met.**	**Major**	**A**	**NI**	**U**	**N/A**		

5.2	**Pre-Production Planning**							
	The factory shall define and implement procedures to conduct pre-production planning meetings to ensure product can be made to meet safety, legal, and quality requirements.							
	5.2.1	**Pre-production meetings shall be conducted and attended by relevant management/staff prior to new products being produced and any subsequent change in design or materials shall be evaluated and approved to ensure safety, legal and quality requirements are met.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	5.2.2	**Process control plan shall be developed from the pre-production meeting to include critical control points for product safety and legality. Reference should be made as appropriate to product specifications, machinery set-up, personnel competency/training needs, etc.**	**Major**	**A**	**NI**	**U**	**N/A**	
	5.2.3	**Factory shall define how changes to the process control plan are approved and implemented to ensure product safety, legality, and quality requirements are met.**	**Major**	**A**	**NI**	**U**	**N/A**	

5.3	**Molding Process (Please rate N/A if there is no molding process)**							
	5.3.1	**Trial production shall be launched against standards and approved samples prior to actual production/intervention.**	**Minor**	**A**	**NI**	**U**	**N/A**	
	5.3.2	**Machine operating parameters setting shall be determined and validated according to the control plan.**	**Major**	**A**	**NI**	**U**	**N/A**	
	5.3.3	**Molding parameters (cycle time, temperature, pressure, short shots, etc.) shall be monitored and corrective action taken as necessary.**	**Major**	**A**	**NI**	**U**	**N/A**	
	5.3.4	**The use of reground materials shall be controlled according to the control plan.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	5.3.5	**Mold trimming shall be conducted in a well lighted area with specifications and using proper trimming tools and equipment to ensure control of sharp edges.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	5.3.6	**Procedures and controls shall be in place to check and monitor the quality of finished parts (correct tooling, parts dimensions, reference marks, clearness, reground rate, etc.).**	**Major**	**A**	**NI**	**U**	**N/A**	

5.4	**Stamping/Engraving/Casting Process (Please rate N/A if there is no stamping / engraving / casting process)**							
	5.4.1	**Procedures and controls shall be in place to check for the quality (correct tooling, deformation, defects, cleanness, clearness and correctness, etc.).**	**Major**	**A**	**NI**	**U**	**N/A**	
	5.4.2	**Stamp, engraving, or casting shall be inspected for the quality (deformation, defects, cleanness, clearness and correctness, etc.). Particular attention shall be paid to avoid sharp points and edges.**	**Critical**	**A**	**NI**	**U**	**N/A**	
5.5	**Gluing Process (Please rate N/A if there is no gluing process)**							
	5.5.1	**The application (and mixing process if applicable) process shall be controlled to ensure consistent coverage and application of glue/solvent to pieces being joined (e.g. automated vs. syringe, stick, etc.)**	**Major**	**A**	**NI**	**U**	**N/A**	
	5.5.2	**The break open procedure shall be in use to verify amount of glue or solvent.**	**Minor**	**A**	**NI**	**U**	**N/A**	
	5.5.3	**Procedures and controls shall be in place to check and monitor part quality (correct tooling, deformation, defects, crystallization, ventilations, temperature control and relative humidity, etc.). Particular attention shall be paid to avoid generation of small parts or edges.**	**Critical**	**A**	**NI**	**U**	**N/A**	

5.6	**Sonic Welding Process (Please rate N/A if there is no sonic welding process)**							
5.6.1	**Operational document for the welding parameters (frequency, hold time, weld time, pressure) shall be available and in use.**	**Major**	**A**	**NI**	**U**	**N/A**		
5.6.2	**Procedures and controls shall be in place to check and monitor part quality (deformation, defects, temperature control and relative humidity, etc.). Particular attention shall be paid to avoid small parts and sharp edges.**	**Critical**	**A**	**NI**	**U**	**N/A**		
5.7	**Screwing Process (Please rate N/A if there is no screwing process)**							
5.7.1	**Operational document for the screwing process (torsion, sequence, workmanship, size, length) shall be available and in use.**	**Major**	**A**	**NI**	**U**	**N/A**		
5.7.2	**Procedures and controls shall be in place to check and monitor part quality (correct tooling, deformation and defects, etc.). Particular attention shall be paid to avoid small parts and sharp edges.**	**Critical**	**A**	**NI**	**U**	**N/A**		
5.8	**Manual Assembly (Please rate N/A if there is no manual assembly process)**							
5.8.1	**The factory shall define and implement a procedure and /or working instructions for the manual assembly process.**	**Major**	**A**	**NI**	**U**	**N/A**		
5.8.2	**Controls of components shall be in use before and after assembly. Particular attention shall be paid to avoid defects which may result in hazard.**	**Major**	**A**	**NI**	**U**	**N/A**		

5.9	**Fabric, Trims, Accessories, Eyeing/Buttoning Process (Please rate N/A if fabric, trims, buttons are not used)**							
5.9.1	**Fabrics shall be tested against applicable safety, legality, and quality related standards and approved samples prior to cutting.**	**Major**	**A**	**NI**	**U**	**N/A**		
5.9.2	**The fabric parts, trims, eyes/buttons shall be tested before and after application to ensure the compliance with specific safety standards.**	**Critical**	**A**	**NI**	**U**	**N/A**		
5.9.3	**Eyeing/buttoning lines shall be organized in accordance with process flow, with adequate specifications.**	**Major**	**A**	**NI**	**U**	**N/A**		
5.10	**Stuffing Process (Please rate N/A if there is no stuffing process)**							
5.10.1	**Stuffing/stuffed parts shall be weighted and inspected against the standards/specification requirements.**	**Major**	**A**	**NI**	**U**	**N/A**		
5.10.2	**Controls shall be in place to check and monitor part/product quality (humidity, weight of stuffing, dirt, and hygiene, etc.).**	**Major**	**A**	**NI**	**U**	**N/A**		
5.11	**Miscellaneous Process (Please rate N/A if there is no miscellaneous process)**							
5.11.1	**The factory shall define and implement a procedure and /or working instructions for any other miscellaneous production process.**	**Major**	**A**	**NI**	**U**	**N/A**		
5.11.2	**Controls of components / semi-products shall be defined and implemented for such miscellaneous production process. Particular attention shall be paid to avoid defects which may result in hazard.**	**Major**	**A**	**NI**	**U**	**N/A**		

6	**FINAL PRODUCT CONTROL AND TRACEABILITY**							
	The factory shall define and implement procedures to effectively control final product and traceability to assure conformance with safety, legal and quality requirements.							
6.1	**Final Inspection, Labeling and Packing**							
6.1.1	**Pre-final and final inspection shall be conducted as per customer requirements.**	**Major**	**A**	**NI**	**U**	**N/A**		
6.1.2	**Products shall be inspected for workmanship prior to packing.**	**Minor**	**A**	**NI**	**U**	**N/A**		
6.1.3	**Labeling shall meet all regulatory requirements for the country in which product is sold.**	**Critical**	**A**	**NI**	**U**	**N/A**		
6.1.4	**Products shall be packed according to packing instruction/customer requirements.**	**Minor**	**A**	**NI**	**U**	**N/A**		
6.2	**Reference Samples**							
	The factory shall ensure that reference samples, or component samples are held and are available for appropriate personnel or referral.							
6.2.1	**Reference samples shall be retained as per customer's requirements.**	**Major**	**A**	**NI**	**U**	**N/A**		
6.2.2	**Reference samples shall be stored in conditions to maintain product integrity.**	**Minor**	**A**	**NI**	**U**	**N/A**		

6.3	**Product Identification and Traceability**							
	The factory shall define and implement a system to effectively trace materials from raw materials, components, work in progress, and finished product throughout the manufacturing process to ensure traceability as needed.							
	6.3.1	**All final product shall be identified as required by customer or legal requirement of the country of which the goods will be sold (i.e. date code and factory.) and identification shall be on the master carton to enable traceability to production.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	6.3.2	**Records shall indicate that finished products are released by authorized personnel.**	**Major**	**A**	**NI**	**U**	**N/A**	

7		**TIA SAFETY MARK**						
		The factory shall define and implement procedures for use of the toy safety mark on final product and traceability to assure conformance with requirements established by the adminstrator.						
	7.1.1	**The factory shall meet all requirements for use of the toy industry safety mark as established by the administrator.**	**Critical**	**A**	**NI**	**U**	**N/A**	
	7.1.2	**The factory shall validate the use of the toy industry safety mark on final products meets all requirements of the administrator prior to shipment release.**	**Critical**	**A**	**NI**	**U**	**N/A**	

Need to add questions about use of certification Mark (we need more details first). Suggest certification mark questions be limited to verification of authorization to bear the mark prior to release of product and how non-conforming product which bears the mark will be controlled.

Appendix 4: Guidance Document for Factory Audit Checklist

NOTE: Guidance *to be used in conjunction with Factory Audit Checklist (Appendix 3)*

Section # & Clause #		***Descriptions***
1		***QUALITY MANAGEMENT STANDARD (QMS)***
1.1		***Organizational Structure, Responsibility and Management Authority***
	1.1.1	***The factory shall define and communicate the levels of responsibility and authority for staff that may affect product safety, legality and quality.***
	Guidance	All documentation of the organization structure and different functions with corresponding responsibility and authority of all personnel who affect product safety, legality and quality shall be evident, understood, and implemented.
	Examples evidence	• Job description • Organization chart • Interview with management

Section # & Clause #		Descriptions
2		**FACTORY FACILITIES (GOOD MANUFACTURING PRACTICE)**
2.1		***Building Exterior and Interior***
	2.1.1	***Building exterior and interior shall be maintained in good condition to prevent deterioration of or damage to materials and products.***
	Guidance	The factory premises shall be well maintained, of sound construction, and suitable for the intended purpose with regard to the risk of product contamination and product. The premises condition shall not post any risk, which may jeopardize or contaminate the products during the production, transportation and storage.
	Examples evidence	Could focus on the production floors, at the packaging areas, and at the warehouse for: • Leakage on the roof, • Broken window glass, • Without window screens, • Cement paste falling off from interior walls, • Broken lighting facilities,
2.2		***Layout/Product Flow***
	2.2.1	***The process flow from receiving to shipping shall be designed to prevent non-conforming product or contamination.***
	Guidance	The sequence of the production process shall be designed in a manner to ensure effective process and product control, which shall take into consideration to prevent causing non-conforming product and contamination when handling and storage of product throughout production.
	Examples evidence	• Production process flow chart, • Critical path of production, • Floor plans/layouts, • Defined tracks/routes for materials movement, • Designated areas for materials, semi-products, final products and non-conformities
2.3		***Equipment and Maintenance***
	2.3.1	***Equipment and production machinery shall be properly designed, constructed, and installed to prevent non-conforming product during all production capacities.***
	Guidance	Equipment and/or production machinery shall be suitably designed for the intended purpose and shall be used so as to minimize the risk of contamination and damage of product.
	Examples evidence	• Master list of the major machinery, • Machinery and/or equipment commissioning records, • Commissioning records of major production machinery

Section # & Clause #		Descriptions
	2.3.2	***The factory shall define and conduct preventive maintenance programs to ensure all equipment and production machinery are adequately maintained to operate safely and efficiently.***
	Guidance	A system of planned maintenance shall be in place covering all items of equipment/machinery, which are critical to product safety, legality, and quality. • Periodic – daily, weekly, monthly, and yearly – maintenance schedule • Preventive maintenance plan • Safety checkpoints defined on major production machinery
	Examples evidence	• Maintenance procedures/work instructions, • Maintenance schedule & records, • Sub-contracted service records, • Maintenance plan, • Routine service records,
	2.3.3	***The factory shall ensure that the safety of products is not affected during maintenance or housekeeping operations.***
	Guidance	Suggested maintenance or housekeeping operations: • Shut down period; • Weekend; • After end of shift; • Or during operation hours, but control measures are in place to prevent contamination risks.
	Examples evidence	• Maintenance procedures/work instructions, • Maintenance schedule & records, • Sub-contracted service records. • Observe the on-site maintenance (if any) and make sure proper protection and/or segregation are given to the products.
2.4		***Pest Control***
	2.4.1	***The factory shall either contract the services of a competent pest control organization, or shall have trained personnel, for the regular inspection and treatment of premises to deter and eradicate infestation.***
	Guidance	The factory shall periodically conduct pest control activities either internally or sub-contract to external service provider in order to minimize the risk of contamination from pest.
	Examples evidence	• Pest control records • Internal personnel training records regarding specific pest control • Service contract signed with external body • Interview with the designated personnel of pest control, if needed • Fly killer • Pesticide used and corresponding usage instruction

Section # & Clause #		Descriptions
	2.4.2	***No evidence shall be present of pest activity that could compromise product safety, legality, and quality.***
	Guidance	No pest shall be observed during the on-site factory tour.
	Examples evidence	By observation during the factory tour and check for pest activity on potential pest harborage areas, i.e. • Warehouse, • Production floors, • Catering facilities,
	2.4.3	***Pest activity report with corrective actions shall be completed at defined intervals and satisfactorily verified.***
	Guidance	The factory shall perform corrective action in the case of products being contaminated from pest intrusion with proper follow up and effectiveness evaluation on the action conducted.
	Examples evidence	• Corrective action records on pest activity • Follow up records
2.5		***Chemical Control***
	2.5.1	***All Material Safety Data Sheets (MSDS) or equivalent documents shall be on file and up to date.***
	Guidance	The use of chemicals shall be fully documented with • Specification, • MSDS, • Handling procedures and/or instructions in order to control or minimize the risk of chemical contamination or damage of product.
	Examples evidence	• MSDS with sound filing and posted at the point of use and storage • Relevant documents available at the point of use and storage
	2.5.2	***All chemical types shall be handled by authorized / trained staff.***
	Guidance	Special training for chemical handling shall be provided to responsible personnel. Designated personnel shall be authorized and identified for chemical materials handling.
	Examples evidence	• Handling procedures and/or instructions in written, • Training records, • Specific PPE,

Section # & Clause #		Descriptions
	2.5.3	***All chemical types are appropriately labeled and segregated during storage and separated from raw materials and finished products by a physical barrier.***
	Guidance	Appropriate facilities and procedures shall be in place. Sound segregation and identification must been applied to chemicals throughout the factory.
	Examples evidence	• Specific signage, • Designated storage area(s) for chemicals at usage • Designated and isolated lockable store room for chemical materials • By observation during the factory tour and check the labeling of chemicals used in the production workshop.
2.6		***Segregation and Stock Rotation***
	2.6.1	***Procedures shall be in place to prevent the contamination of raw materials, packaging and finished products.***
	Guidance	Implementation of suitable and effective material segregation practice/procedures at storage areas to prevent possible cross contaminations of raw materials, packaging and finished products.
	Examples evidence	• Written procedures and/or working instructions • Controlled material and product warehouse • Designated personnel for materials, packaging, and products receipt-&-release • Neat and clean storage condition / environment • By observation during the factory tour and check for proper implementation of segregation on the raw materials, packaging and finished products.
	2.6.2	***Procedures shall be in place to assure materials and products are used prior to end of shelf life (as applicable) where safety, legality, or quality will be affected.***
	Guidance	Proper stock rotation procedure shall be applied to raw materials on best practice with regarding to materials' shelf life. Practice of First-In-First-Out.
	Examples evidence	• Material receipt and release records • Materials stock cards • Clear identification on materials

Section # & Clause #		Descriptions
2.7		***Foreign Body Contamination***
	2.7.1	***The factory shall define and implement procedures for the control and monitoring of sharp items such as blades and needles, which shall be collected and documented before replacements are issued.***
	Guidance	The Factory shall ensure all necessary steps, by using principle of hazard analysis, are taken to identify, avoid, eliminate or minimize the risks of metal or other foreign body contamination, e.g. broken needles, trimmers, broken glass...etc. For prevention of glass contamination, special procedure shall be in place for lighting facilities' cleaning, replacement and/or maintenance. As a minimum requirement, final product assembly / storage and packaging areas shall apply the glass control measures.
	Examples evidence	• Sharp tool control (including needle replacement) policy, • Inspection records, • Metal detector calibration & maintenance records, • Glass control procedure, • Corrective action records for foreign body detection / control failure • Broken-needle / needle replacement records • Wire-protect glass windows • Lightings with protective shelter
	2.7.2	***The factory shall establish and implement procedures for calibration, operation, and routine monitoring when a metal or foreign body detector is used.***
	Guidance	For the factory with sewing process available, factory shall implement effective metal detection measures to prevent product contamination by needles or sharp metal. • Schedule of calibration • Operation procedure / working instruction • Designated area for segregation
	Examples evidence	In case of metal detector presents, the factory shall establish appropriate procedures with respect to calibration, operation, and routine monitoring of the equipment. • Metal detection procedure • Metal detector operating procedure • Metal detector calibration procedure and records • Metal detector routine inspection records • On-site checking on the functionality of the metal detectors.

Section # & Clause #		Descriptions
	2.7.3	***The factory shall establish reporting procedures and implement remedial action, in the event of the monitoring and testing procedure identifying any failure of the metal or foreign body detector. These will include the recall, quarantining and re-inspection of all product produced since the last acceptance test of the metal or other foreign body detector.***
	Guidance	In case of fault products found or machine broke-down, the products shall be traced back to the last acceptance test / proper calibration of the metal detector. Appropriate quarantine procedure shall be applied to prevent the contaminated products being shipped out, and conduct re-inspection if necessary.
	Examples evidence	• "Metal detection failure" handling instruction • "Re-inspection" records • Disposal records
	2.7.4	***Records of metal or foreign body detection shall be maintained so that the product is fully identified and traceable.***
	Guidance	The factory shall maintain detailed metal / foreign-body detection records for the products released.
	Examples evidence	• Detection records with product information for traceability
	2.7.5	***The factory shall have a policy preventing the wearing of potentially contaminating articles such as jewelry, earrings, etc.***
	Guidance	For the workers, jewelry policy shall be applied and followed to prevent the jewelry wore by the workers from becoming the contamination to the products. • Policy distributed / announced • Control checks set prior entering the production floor
	Examples evidence	• No earring, necklace and bracelet shall be wore in the production workshops • Only plain wedding rings would be allowed

Section # & Clause #		Descriptions
2.8		***Control of Non-Conforming Materials***
	2.8.1	***The process for segregation and disposition of non-conforming materials shall be defined, including the authority levels for segregation and disposition (rework, scrap, and waiver).***
	Guidance	The Factory shall ensure all out of specification product is clearly identified, labeled and quarantined. Authorization must be clearly defined for disposition and handling of the defects. Specific quarantine / storage areas shall be designated. Proper labels (including the toy industry safety mark) and/or signage shall be posted on the non-conforming products. The NC materials control procedure shall include: • Corrective action implemented to avoid recurrence of non-conformances • Document maintained for action taken, • Recall procedure, if any
	Examples evidence	• Re-work and/or re-inspection records, • Disposal records, • Corrective action records, • Non-conformance handling procedures, • Waiver notice,
	2.8.2	***All non-conforming materials shall be clearly identified and segregated until disposition.***
	Guidance	The factory shall effectively identify and segregate the non-conformity materials / products throughout the production process, from material receipt to final product release.
	Examples evidence	• By observation during the factory tour and check for proper implementation of segregation on the non-conforming products.
	2.8.3	***All non-conforming product shall be handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.***
	Guidance	The factory shall define handling procedure / working instruction for the major non-conformities to ensure meeting the set requirements. The procedure shall also apply to the products had been released / shipped out to customers.
	Examples evidence	• Disposal records • Waiver notice • By observation during the factory tour and check for proper handling and disposal of the non-conforming products.

Section # & Clause #		Descriptions
	2.8.4	***The factory shall have a procedure for disposing of nonconforming product with toy industry safety mark on it or its packaging.***
	Guidance	
	Examples evidence	
	2.8.5	***Effective corrective actions shall be implemented to avoid recurrence of non-conformance and adequate documentation kept of the action taken.***
	Guidance	The factory shall investigate the root cause of the non-conformity and perform effective corrective and preventive actions address the non-conformity in order to eliminate the possibility of recurrence.
	Examples evidence	• Corrective action records • Corresponding effectiveness evaluation on the action taken
2.9		***Calibration and Control of Measuring and Monitoring Devices***
	2.9.1	***The factory shall identify all measuring equipment used to monitor critical/major elements of product safety, legality, and quality.***
	Guidance	The factory shall identify measuring equipment used to monitor critical control points and product safety and legality. The identified measuring equipment shall be calibrated, to a recognized national standard. Where a traceable calibration is not possible, the factory shall demonstrate the basis by which standardization is carried out. • New equipment and installations are calibrated and validated prior to use; • Calibration is carried out by a competent person who has the authority to do so; • Equipment used with calibration label,
	Examples evidence	• Calibration schedule / plan, • Procedures, • Re-calibration / replacement records, • Training record / certificate of the calibration staff,
	2.9.2	***Measuring and monitoring equipment shall be routinely calibrated to recognized national standards.***
	Guidance	This procedure shall include; • Frequency of calibration of existing equipment; • Standard methods specify acceptance criteria; • National standards are used;
	Examples evidence	• Standard document • Calibration procedure / instruction • Calibration records, either internal or external certificates

Section # & Clause #		Descriptions
	2.9.3	***Records of equipment calibration and re-calibration shall be maintained.***
	Guidance	The factory shall maintain detailed calibration records to assure the equipment used are fully compliance and traceable.
	Examples evidence	• Calibration records, either internal or external certificates • Calibration schedule • Calibration certificates
	2.9.4	***Measuring and monitoring equipment found to be out of calibration shall be immediately re-calibrated or replaced and records of event shall be documented.***
	Guidance	• Re-calibration; • Replacement, if needed, of the defect equipment; • Proper records on the defected equipment and products;
	Examples evidence	• Re-calibration or replacement records; • Identification on the defect equipment; • Defined handling procedure for the potential non-conforming products with records;
	2.9.5	***Records shall be maintained when the factory has taken appropriate action (product accounted for) for any product affected from out of calibration measuring equipment.***
	Guidance	Proper action shall be taken when equipment is found to be out of specified accuracy; • Re-call of the released products, which were measured by the defected equipment; • Quarantine the defect products at designated area with proper identification, • Corrective action shall be taken
	Examples evidence	• Product re-call / specific handling records for defect equipment issue • Corrective action records

Appendix 5: Corrective Action Plan template

Factory Conformity Assessment
CORRECTIVE ACTION PLAN

NOTE: *Template to be used in conjunction with Factory Audit Checklist and Guidance Document (Appendix 3 and Appendix 4)*

Report Number: _____

Factory name: _____

Official Contact: _____

Person Interviewed: _____

Audit Purpose: _____ Initial _____ Follow-up _____ In-Production

_____ Unannounced _____ Other (Please Specify)

Conclusion: _____ Pass

_____ Improvements Required (*Continued production subject to increased testing or inspection pending timely corrective action requested and successful follow-up audit*)

_____ Fail

If re-audit required, specify date scheduled: _____

Audit Body Name: _____ Phone: _____

Address: _____

Auditor: _____ Title: _____ Date: _____

Evaluated by: _____ Date: _____

Approved by: _____ Date: _____

Executive Summary: _____

_____

_____

Compliance with the following sections is necessary for conformance with *TIA-ANSI TSCI Factory Audit Checklist and Guidance Document (Appendix 3)*. Conformance is expected in the shortest time practicable in accordance with Priority Code;

Section	Acceptable?	**If NO,** **detail Corrective Action requested** **(attach additional pages if necessary)**	**Priority Code** (see below*) **Implementation Date**
1. General Information and organization	YES [ ] Improvement Required [ ] NO [ ]		
2. Quality Management System	YES [ ] Improvement Required [ ] NO [ ]		
3. Factory Facilities	YES [ ] Improvement Required [ ] NO [ ]		
4. Resource Management	YES [ ] Improvement Required [ ] NO [ ]		
5 Incoming Material Control	YES [ ] Improvement Required [ ] NO [ ]		
6. Process and Production Control	YES [ ] Improvement Required [ ] NO [ ]		
7 Final Product Control and Traceability	YES [ ] Improvement Required [ ] NO [ ]		

* PRIORITY CODES TO SPECIFY FOR CORRECTIVE ACTION REQUESTS

A	*Impact:*	High	*Feasibility:*	Easy	Immediate action required, Tier 3 testing
B	*Impact:*	Medium	*Feasibility:*	Easy	Complete by 1 month, Tier 2 testing
C	*Impact:*	High	*Feasibility:*	Hard	Complete by 3 months, Tier 3 testing
D	*Impact:*	Medium	*Feasibility:*	Hard	Complete by 6 months, Tier 2 testing
Z	*Impact:*	High	*Feasibility:*	Very Hard	Provide work plan by X months, Tier 3 testing