# Pilot Impact Assessment of the Inherent and External Entrapment Protection Requirements for Residential Garage Door Operators in *UL 325, the Standard for Door, Drapery, Gate, Louver, and Window Operators and Systems*

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## Introduction

### Purpose

This objective of this pilot study was to investigate the impacts of the inherent and external entrapment protection requirements for residential garage door operators contained in *UL 325, the Standard for Door, Drapery, Gate, Louver, and Window Operators and Systems (Revised 12/31/1991)* on public health and safety. Available evidence was collected and examined to render a judgment on the efficacy of the inherent and external entrapment protection requirements in UL 325 for residential garage door operating systems in the United States. Furthermore, it is expected that the methods used to assess the impacts of standards will continue to improve through this pilot study and progress toward a more efficient method of standards impact assessment.

### The Dual Entrapment Protections Requirement

*UL 325, the Standard for Door, Drapery, Gate, Louver, and Window Operators and Systems* was first published in April 1973, with multiple revisions and seven editions published since. The requirements for inherent and external entrapment protection for residential garage door operators, hereafter referred to collectively as the “dual entrapment protection requirements,” were introduced in the December 31, 1991, revision of the Standard with an effective date of January 1, 1993.

## The Assessment Process

The pilot study was guided by the Center for Disease Control (CDC) *Framework for Program Evaluation in Public Health*. The CDC Framework consists of a six-step approach (Figure 1):

1) Engage Stakeholders
2) Describe the Process
3) Focus the Evaluation Design
4) Gather Credible Evidence
5) Justify Conclusions

6) Ensure Use and Share Lessons Learned

A Modified Delphi Technique was employed as the Stakeholder Working Group's working process. The technique allowed individuals to work independently and at the times of their choosing. The process consisted of several rounds, wherein each round individual subject matter experts (SMEs) provided initial anonymous input, then considered the aggregated and anonymized inputs of the others, and finally revised and resubmitted their own input. This process was utilized for each stage of the Framework requiring the Working Group's input: Describing the Process, Focusing the Evaluation Design, Gathering Credible Evidence. The Delphi rounds continued until consensus was reached or three rounds had been completed – whichever came first. If at the end of three rounds no consensus had been reached, a simple majority or mean value was applied.


Figure 1: Evaluation Framework

From: U.S. Department of Health and Human Services and Centers for Disease Control and Prevention. (2011). *Introduction to Program Evaluation for Public Health Programs. A Self-Study Guide*, 2005.

## Engaging Stakeholders

To begin the process, a team representing the stakeholders of the Standard were assembled to form the Stakeholder Working Group that guided the assessment process and approved the results. The seven stakeholders participating in the working group included the Technical Committee Chair, the Technical Committee Project Manager, the Principal Engineer from UL Solutions, a representative from a testing, inspecting, and certifying organization, a manufacturer's representative, a representative from the Door and Access System Manufacturers Association, and a member of UL Standards & Engagement's international team. The working group's main activities were to describe the program, focus the evaluation, and justify the conclusions. By including stakeholders in the planning and execution of the assessment process, a variety of perspectives were incorporated into the assessment beyond those of UL Standards & Engagement.

## Describing the Process of Standards Impact

In the case of assessing the impact of a voluntary consensus standard (or a subset of its requirements, as is the case here) on public health and safety, a description of the process is needed to explain the connection between publication of a set of design or construction requirements for products and the changes in the occurrences of incidents with these products in future. The description of the process defines all the stages which a standard goes through from publication to adoption – when the conforming products find their way into use by the public. A logic model is the graphical depiction of the entire adoption process, including the stages of the process and the *inputs* and *outputs* of each stage. *Inputs* consist of the external influencers on the activities of the product manufacturers in that stage of the adoption process. These are outside factors that provide incentives or disincentives for the manufacturer to become aware of and adopt the standard. *Outputs* are the indicators of the manufacturer's activities in that stage.

The Revised Voluntary Standards Adoption (RVSA) model depicted in Figure 2 was accepted as the logic model for this assessment. The RVSA model captures the adoption process of a voluntary product safety standard, beginning with the creation of the standard/revision, proceeding on to growing awareness of the standard across an organization, followed by the adoption of the standard and the application of the requirements in the design and/or manufacture of affected products, and ending with conforming products entering the market and causing eventual changes in the frequency and/or severity of adverse incidents.

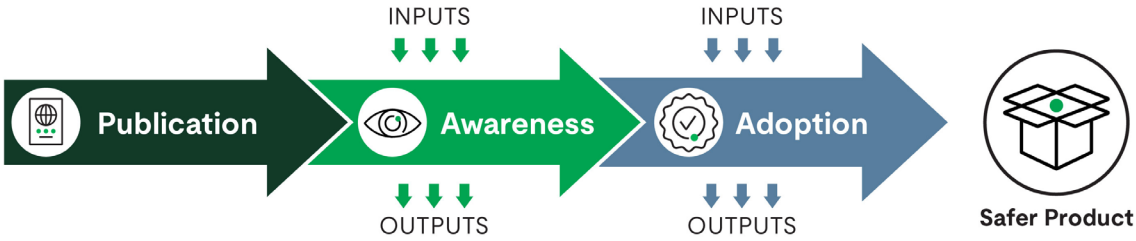


Figure 2: Revised Voluntary Standards Adoption (RVSA) Model

## Focusing the Evaluation Design

The focus of this impact assessment is the effect of the dual entrapment protection requirements of UL 325 on entrapment incidents with electric garage door operators in the United States. The outcome measure for this assessment was the change in entrapment incidents meeting these criteria during the ten-year period following the publication of the third edition of UL 325 on December 31, 1991, compared to a baseline ten-year period preceding the publication of the revision. This extended time span for the pre-post analysis is included to

provide sufficient time after the publication for electric garage door operators conforming to the “dual entrapment protection requirement” to reach widespread use in the population.

Data collected from the stages of the RVSA model can provide the evidence to credibly infer that these changes in entrapment incidents are due, at least in part, to the dual entrapment protection requirements of UL 325 and not some other potential explanation. Data from the stages of adoption became the leading indicators in the assessment, specifically the inputs and outputs to the stages of adoption. To be accepted as leading indicators, the inputs and outputs identified through the RVSA model needed to be quantifiable and reliable. In this case, quantifiable means they can be expressed numerically. Many inputs and outputs are already in a numeric format, but others can be converted through scaling or even through representation by a binary indicator (yes = 1 or no = 0). For the purposes of the study, reliability implies that the input has the same influence on all manufacturers in that same stage of the adoption process, or that the output indicates equivalent activity for all manufacturers in that same stage.

### Gathering Credible Evidence

There were a number of inputs and outputs initially identified by the working group for inclusion as leading indicators. However, due to the publication of the third edition of UL 325 occurring more than 30 years ago, and the state of information technology at that time (before widespread use of the internet, cloud computing, etc.), much of the data sought for the initial leading indicators were not available. In the end, trade association publications on UL 325 (awareness inputs), and the inclusion of the dual entrapment protection requirements into federal regulation (adoption inputs) were employed as leading indicators in this study.

The source of the outcome data were the U.S. Consumer Product Safety Commission (CPSC) databases: the Consumer Product Risk Management System (CPRMS), and the National Electronic Injury Surveillance System (NEISS). The CPRMS database consists of data collected from three independent sources: Death certificates (DTHS), In-Depth Investigations (INDP), and Injury/Potential Injury Incident (IPII) Files. The DTHS data set consists of death certificate files from each state health department, provided to the CPSC in cases where consumer products were found to be involved in the deaths. The INDP file contains summaries of reports of investigations into events surrounding product-related injuries or incidents. The IPII file contains summaries, indexed by consumer product, of CPSC Hotline reports, product related newspaper accounts, reports from medical examiners, and letters to CPSC. NEISS data are collected from of a sample of hospitals that are statistically representative of hospital emergency rooms nationwide. From this data, estimates of the numbers of injuries associated with consumer products and treated in hospital emergency departments are made.

## Findings

### Leading Indicators

Trade association publications on UL 325 as inputs into the awareness stage and the inclusion of the dual entrapment protection requirements of UL 325 into federal regulation as inputs into the adoption stage were the leading indicators selected for this study. Five examples of professional communications referencing entrapment protection were located that were dated between spring 1991 and winter 1993. Two of these explicitly discussed the dual entrapment protection requirements in UL 325 and/or federal regulations (2 and 4 below). Altogether, these communications provide evidence of the growing awareness of the hazard of entrapment in general, and, specifically, the dual entrapment protection requirement of the third edition of UL 325.

1. **DORCMA offers statement on testing for automatic reverse features. (1991).** ***Garage Door Business, Spring, 1991*** Mentions the UL 325 third edition compliance requirement with UL automatic reverse requirements.
2. **Legislative activity on garage door operator safety continues into 1991. (1991).** ***Garage Door Business, Spring, 1991*** Mentions third edition compliance with existing entrapment protection requirements of UL 325, the "dual entrapment protection" requirements of UL325 to be required by federal regulation by Jan 1, 1993, and the Minnesota law requiring garage door openers to comply with auto reverse function of UL 325 to be repaired.
3. **Industry groups, safety commission kick off operator safety campaign. (1991).** ***Garage Door Business, Spring, 1991*** Discusses forthcoming industry-government public information campaign on garage door operator safety, mentions third edition compliance with existing entrapment protection requirements of UL 325, and advises to test operators for UL 325 automatic reverse function
4. **New regulations on testing and servicing openers now in effect. (1991).** ***Garage Door Business, Winter, 1992*** Mentions Jan 1, 1993, compliance date for "dual entrapment protection" requirements in federal regulation
5. **Legal insights: Recent legislative changes affect dealers in Indiana and California. (1993).** ***Garage Door Business, Winter, 1993*** - Mentions requirements to comply with UL 325 third edition (May 1988) in Indiana law

The most influential leading indicator of the impact was the inclusion of the dual entrapment protection requirements into federal regulation in the 16 CFR Part 1211—Safety Standards for Automatic Residential Garage Door Operators, effective January 1, 1993.[1] The CPSC codified the dual entrapment protection provision of the third edition of UL 325, making it a mandatory feature for all residential garage door operators sold in the U.S. after the effective date. This indicator ensures adoption of the requirement across manufacturers, directly linking the design requirements of the Standard to the public health and safety outcomes that followed.

[1] Federal Register, Vol. 57, No. 245, Monday. December 21, 1992. 60449-60456

## Outcomes

When we look at the garage door entrapment data captured by NEISS and CPRMS, we see two different patterns emerging. Within the NEISS data, we see an increase in the number of entrapment injuries treated in the sample of emergency departments after the enactment of the dual entrapment protection requirements (Table 1). However, there does not appear to be any meaningful increase in entrapment injuries as a percentage of garage door injuries. The increase in entrapment injury count is likely due to an increased number of electronic residential garage door operating systems in use in the U.S., and not an increased risk of entrapment incidents by electronic residential garage door operating systems.

| | **Total Garage Door Injuries** | **Total Entrapment Injuries** | **% Entrapment Injuries** |
|---|---|---|---|
| **All Years** | 886 | 32 | 4% |
| **≤ 12/31/1991** | 279 | 8 | 3% |
| **> 1/1/1992** | 607 | 24 | 4% |

Table 1: NEISS Data on Entrapment Injuries Seen in ED

By examining the CPRMS data, a clearer picture of decreasing risk of injury from electronically operated residential garage doors emerges (Table 2). The total number of entrapment incidents drops precipitously, from 104 for the 10 years preceding the introduction of the requirement, to 66 in the 10 years following – a nearly 37% decrease. Looking at entrapments as a percentage of all incidents involving garage doors, a decrease of 51% (37% to 18%) can be observed between the decade preceding and the decade following the introduction of the requirements. Looking only at fatalities resulting from entrapment incidents, an equally impressive decrease is seen with fatal incident counts dropping from 63 prior to the requirement to 20 in the ten years following – a 68% decrease. Entrapment fatalities as a percentage of entrapment incidents drop from 61% to 30% – representing a 51% decrease.

| | **Total Garage Door Incidents** | **Total Entrapments** | **% Entrapments** | **Fatal Entrapments** | **% Fatal Entrapments** |
|---|---|---|---|---|---|
| **All Years** | 645 | 170 | 26% | 83 | 49% |
| **≤ 12-31-1991** | 279 | 104 | 37% | 63 | 61% |
| **≥ 1-1-1992** | 366 | 66 | 18% | 20 | 30% |

Table 2: CPSRMS Data on Entrapment Incidents Overall

## Limitations

There exists an ongoing challenge regarding the completeness and representativeness of the data available for the outcome measures: injuries and incidents arising from electric garage door operators in the U.S. Although NEISS is a nationally representative probability sample of hospital emergency department (ED) visits, none of the other immediate care options that exist in the U.S. contribute data – such as primary care physicians, urgent care facilities and independent medical clinics. These results question whether the NEISS is representative and complete with respect to capturing non-fatal injuries arising from consumer product incidents occurring in the U.S. The CPRMS database expands the range of data on consumer product incidents beyond solely injuries treated in hospital emergency departments by including data from death certificates and medical examiner reports; reports from some *SaferProducts.gov* submitters; reports provided by other federal agencies, healthcare professionals, public safety entities; and online news sources. However, most of these data sources are wholly dependent on the voluntary actions of the various reporters—raising legitimate concerns about whether the CPRMS data is complete and representative.

The timeframe of the investigation was intended to provide sufficient time after the publication for electric garage door operators conforming to the dual entrapment protection requirement to reach widespread use in the population. However, in the process of conducting this investigation, information was provided by a member of the team indicating these products may have a lifespan of 20 years or more. No information was available regarding the date of manufacture of the operators involved in the incidents examined in this study, therefore it's possible that many of the operators in the field during the 10 years after publication may have been manufactured before December 31, 1991, and therefore not compliant with the new requirements.

The RVSA model serves as a description of the process to establish the relationship between publication of the dual entrapment protection requirements and the changes in the occurrences of entrapment incidents with electric garage door operators. Collection of the leading indicators attests to the credibility of the relationship. However, other possible contributing factors exist that also could have contributed to changes in the outcomes observed. These other potential contributing factors are neither identified nor accounted for in the current investigation.

## Conclusion

The objective of this study was to assess the impact of UL 325 on public health and safety, specifically the influence of the dual entrapment protection requirement, introduced December 31, 1991, on entrapment incidents and injuries. Data on incidents and injuries was collected from CPSC to identify changes in the occurrence in the period from ten years prior to the introduction of the requirements to the 10 years following. In order to attribute any contribution for changes observed in entrapment incidents and injuries to the requirements of UL 325, a model linking the publication of the revision to the occurrence of entrapments was established and data collected in the form of leading indicators to validate it.

A review of entrapment incidents and injuries in the NEISS data shows an increase in the entrapment injury count. However, without any corresponding increase in entrapment injuries as a percentage of all garage door injuries, this increase is more likely due to a rise in electronic residential garage door operating systems in use in the U.S. in the 10 years following the introduction of the dual entrapment protection requirement, and not any increased risk of entrapment from these devices during this time.

By examining the CPSRMS data, a clearer and more consistent picture of decreasing risk of injury from electronically operated residential garage doors appears. Here, a decrease of more than 50% can be seen in incident counts, fatality counts, and entrapment incidents as a percentage of all garage door injuries, and entrapment fatalities as a percentage of all entrapment incidents.

The leading indicators available for use in this study were extremely limited due to the state of computer and information technology in 1991 as well as the number of years that have passed since the dual entrapment requirements were published in the third edition of UL 325 on December 31, 1991. However, the significance of the two leading indicators used -- particularly the inclusion of the dual entrapment requirements of UL 325 into CPSC regulations -- provide compelling evidence that the requirements of UL 325 contribute to the overall decreases in electronically operated residential garage door entrapment incidents and injuries.

Considering the data presented, given the limitations of the study, a credible determination that UL 325 has had a positive impact on public health and safety through the mitigation of the risk of entrapment by electronically operated residential garage door operating systems can be ascertained.

**Lessons Learned**

1. **The value in engaging stakeholders in the assessment process** Specific improvements in the pilot assessment can be attributed to engaging stakeholders during assessment, including the identification of potential sources of data not previously recognized, validation of the RVSA model by subject matter experts, and increased acceptance of assessment results.

2. **The inherent difficulty in assessing impacts of standards long after their publication** A lapse of 31 years led to an inability to collect all of the relevant data that was desired for this pilot study. Future assessments should be conducted in closer proximity to the date of publication of the standard or revision, accepting some lag time allowing for affected products to proliferate among users.

3. **The need to further improve the methods of standards impact assessment** The two years that it took to complete this pilot assessment was excessive. Future assessment activity must find opportunities to shorten the time to completion. The acceptance of the RVSA model for future consumer product impact assessments is one possibility to improve the process by eliminating the need for developing a logic model.