



# Numerical risk tolerance criteria in the United States: A critique of the risk criterion used for the New Jersey Toxic Catastrophe Prevention Act



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## ABSTRACT

Numerical risk tolerance criteria are used around the world in the management of process safety, although federal process safety regulations in the United States do not currently employ such criteria. However, increasingly individual companies are employing numerical criteria motivated by industry practices and standards. Often, precedents are sought in setting criteria. One precedent is the first process safety regulation that was enacted in the United States in the state of New Jersey under the Toxic Catastrophe Prevention Act (TCPA). The regulation that implements the TCPA contains a numerical risk criterion. Companies covered by the regulation must demonstrate through analysis that they comply with the criterion. Unfortunately, the criterion and the procedure for using it are seriously flawed and they should not be used as a precedent by companies or other regulators. This paper identifies various problems with the criterion and describes how to overcome them in order to explain how to avoid mistakes in developing criteria.

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## 1. Introduction

Various countries around the world employ numerical risk tolerance criteria in regulating process safety (CCPS, 2009). However, federal process safety regulations in the United States (US) do not currently employ such criteria (OSHA, 1992; EPA, 1996), although increasingly individual companies are employing numerical criteria driven in part by industry standards such as IEC 61511/ISA 84 (ANSI/ISA—84.00.01—2004, Parts 1–3, (IEC 61511-1 Mod, IEC 61511-2 Mod, IEC 61511-3 Mod)). In setting criteria, regulators and companies often look for precedents. In the US, the only process safety regulations that employ numerical risk criteria are those enacted under the Toxic Catastrophe Prevention Act (TCPA) (TCPA, 1985) in New Jersey and administered by the New Jersey Department of Environmental Protection (NJ DEP) (TCPA, 2012). Thus, it provides the only US precedent for regulators and companies to follow.

Companies operating in New Jersey that have been required to use the TCPA criterion are likely to use it in their operations elsewhere in the US. Furthermore, other companies will copy those with operations in New Jersey, possibly even internationally. However, the TCPA criterion is seriously flawed in multiple ways

and should not be used in its current form. It does not provide a suitable precedent to be followed by companies or other regulators. Unfortunately, the issues with the TCPA criterion are not obvious to the casual practitioner so their propagation is likely. Furthermore, companies and other regulators may well assume that a criterion that has been developed by a regulator is technically correct even when that is not the case.

This paper uses the TCPA criterion to demonstrate some of the pitfalls to be avoided in using numerical criteria. Also, it explains how criteria should be developed correctly, which is critical knowledge for companies at this juncture in the development and use of numerical risk criteria in the US and in other locations where criteria are being considered. The correct development and use of numerical risk tolerance criteria is of vital importance for process safety.

The critique of the TCPA risk criterion was based upon established guidelines for developing quantitative criteria (CCPS, 2009) and pitfalls that have been identified in their development (Baybutt, 2013). Considerations in the critique included:

- Technical foundation and validity.
- Suitability for the regulation of catastrophic accident risk in process plants.
- Comparability with other established regulatory precedents and frameworks.

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The paper first provides an overview of relevant aspects of the TCPA regulation. Next, the nature and origin of the risk criterion used in the TCPA regulation are described. Then, problems with the risk criterion are identified and discussed and modifications are suggested to address the problems.

## 2. The TCPA regulation

The purpose of the TCPA regulation is to “protect the public from catastrophic accidents from chemical releases of extraordinarily hazardous substances (EHS’s) to the environment by anticipating the circumstances that could result in such releases and requiring precautionary and preemptive actions to prevent such releases” (TCPA, 2012). Catastrophic release means “a major uncontrolled emission, fire, or explosion, involving one or more regulated substances that presents imminent and substantial endangerment to public health and the environment” (TCPA, 2012). Toxicity, flammability, explosion, and reactivity hazards applicable to EHS’s must be addressed.

The TCPA regulation requires that companies perform a process hazard analysis (PHA) to identify release scenarios in the same way as for the similar requirement under the Risk Management Plan (RMP) rule promulgated by the U.S. Environmental Protection Agency (EPA, 2006). Specifically, the TCPA regulation requires, “identification of all scenarios of toxic, flammable, and reactive hazards that have a potential offsite impact for the endpoint criteria defined at ... using a consequence analysis, consisting of dispersion analysis, thermal analysis and overpressure analysis, as applicable to the EHS and scenario” (TCPA, 2012 at Section 7:31-4.2(b)3). Parameters for the consequence analysis are specified in the regulation. Consequence analysis means “the determination of the potential consequence of an EHS release on the surrounding population” and involves, “at a minimum, identifying potential populations exposed to the toxic, thermal or overpressure endpoint for each EHS” (TCPA, 2012).

Additionally, the TCPA regulation requires the performance of a risk assessment for the release scenarios. An EHS accident risk assessment means, “a review and safety evaluation of those operations at a covered process which involve the generation, storage, or handling of an extraordinarily hazardous substance” (TCPA, 2012). Risk assessment means, “the evaluation of the results of quantitative analyses to facilitate development of an effective risk reduction plan” (TCPA, 2012). The quantitative analyses shall consist of “an estimate of the quantity, rate and duration of EHS released, a dispersion analysis, a consequence analysis, and an estimate of the probability or frequency of the undesired event” (TCPA, 2012).

For each release scenario that has an offsite impact at or above the values of the endpoint criteria specified in the TCPA regulation, the likelihood of the release occurrence must be determined. If the likelihood is greater than or equal to  $1 \times 10^{-6}$  per year, an evaluation of risk reduction measures which would reduce the likelihood or consequences of an EHS release must be performed. If the likelihood is less than  $1 \times 10^{-6}$  per year, no further assessment is required. Thus, the TCPA regulation employs a risk tolerance criterion for individual hazard scenarios that is expressed as a frequency per annum of adverse impacts to members of the public corresponding to the health effects induced by exposure to a process hazard at the defined endpoint values.

Guidance from the NJ DEP states that the likelihood of each EHS release scenario can be determined using site-specific data that take into account the equipment reliability, human factors, and external forces and events, and generic failure rate and release frequency data from specified literature sources (DEP, 2012). The guidance document states that the release could result from a

single event such as pipe failure, atmospheric tank failure, or unloading hose failure, or from multiple events, all of which must occur to cause the undesired event. In the case of multiple events, the guidance states that fault tree analysis should be used to estimate the likelihood of the event, although event tree analysis actually is needed for the types of multiple events described.

## 3. Nature and origin of the TCPA risk criterion

Insights into the origin of the likelihood criterion used in the TCPA regulation are provided in a response to comments on the re-adoption of the TCPA Program (DEP, 2008). In discussing the likelihood criterion, the NJ DEP stated, “The appropriate value for the likelihood is arguable and controversial. Various sources cite values ranging from  $10^{-3}$  to  $10^{-7}$  as the likelihood values for consequences of concern that are not considered tolerable by the public” (DEP, 2008). Two literature sources were referenced by the NJ DEP for this range of values (Lees, 1996; CCPS, 1998). Also, the NJ DEP stated, “The Department selected  $10^{-6}$  as it is often cited as the level of concern for the frequency of occurrence of a specified consequence to a member of the public” (DEP, 2008).

Furthermore, the NJ DEP stated, “the Department chose  $10^{-6}$  based on its evaluation of other programs that incorporate risk management and assessment. For example, the Air Quality Permitting Program, Bureau of Air Quality Evaluation’s Technical Manual 1003, ‘Guidance on Preparing a Risk Assessment for Air Contaminant Emissions’ details the policy for cancer risk that indicates that  $10^{-6}$  is a negligible risk” and “Both the Air program and the TCPA program evaluate the likelihood of the undesired consequence; for air the risk is getting cancer, and for TCPA it is the likelihood of a catastrophic release that would present an imminent and substantial endangerment to public health and the environment. Therefore, the Department has determined that it is appropriate to use the  $10^{-6}$  likelihood value as a trigger above which an evaluation of risk reduction measures would be performed” (DEP, 2008).

The Technical Manual for the Air Quality Program details the policy for cancer risk (DEP, 2009). It states that risk for carcinogens should be expressed in terms of incremental individual risk and that total population risk should not be calculated. Also it states that it is not necessary to add the risks from the different contaminants being considered. The Technical Manual states that cancer risks less than or equal to one in a million ( $1 \times 10^{-6}$ ) are considered negligible, and cancer risks greater than or equal to  $1 \times 10^{-4}$  are considered unacceptable, while cancer risks that fall between these two values are evaluated on a case-by-case basis. These values are for individual sources of air contaminant emissions at facilities. No units are specified but the values correspond to industry standards expressed on a per lifetime basis (Kelly, 2005).

The New Jersey Air Quality Permitting Program also specifies facility-wide risk criteria. Total cancer risk (from all permitted sources at a facility) that is less than or equal to ten in a million ( $1 \times 10^{-5}$ ) is considered negligible, and total cancer risk greater than one thousand in a million ( $1 \times 10^{-3}$ ) is considered unacceptable. Facilities with a total cancer risk between ten in a million ( $1 \times 10^{-5}$ ) and one hundred in a million ( $1 \times 10^{-4}$ ) are required to pursue a long-term risk minimization strategy while facilities with a total cancer risk between one hundred in a million ( $1 \times 10^{-4}$ ) and one thousand in a million ( $1 \times 10^{-3}$ ) also are required to pursue a short-term risk minimization strategy. Essentially, this is an application of the As Low As Reasonably Practicable (ALARP) Principle (HSE; Baybutt, 2014a).

The implication of these risk criteria is that the de manifestus incremental lifetime cancer risk from a facility for a member of the

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