

**A Generic Standard for the Risk Assessment Process:
Discussion on a proposal made by the program committee of the JC – JRC workshop on
‘Promotion of Technical Harmonization of Risk-Based Decision Making’**

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I Abstract.

This paper reviews the background and nature of the ‘generic standard for risk-based decision making’ (Generic Standard) put forward by the Workshop’s Organizing Committee (Committee). Based on this analysis, the authors agree with the Committee’s presumption that adopting a Generic Standard as a structural guideline for focused risk assessment standards in each of the several listed technical areas is feasible, will promote ‘harmonization,’ and will help achieve the several advantages of harmonization outlined in the meeting’s “Guideline for Invited Experts.”

More specifically, the paper makes four main recommendations in regard to the Generic Standard:

- Utilize all four of the Generic Elements, their Sub-elements and Terms employed in the OECD/CARAT hierarchy, originally developed for major accidental releases from fixed facilities, as the conceptual basis of the proposed Generic Standard.
- Use none of the Categories and Descriptors of the CARAT hierarchy as part of the Generic Standard except possibly as examples for the extension of the Generic Standard into specific technical cases.
- However, require that Categories and Descriptors be included in the hierarchy of the standards for specific technical areas, as these features give uniqueness and operational meaning to the risk processes involved in these areas.
- Include provision for the information gathering, retrieval and search features contained in CARAT (References, Tools and Criteria). These features will add value to the goals of the workshop and will promote the wider use of the specialized technical area standards.

II Introduction.

The European Commission’s Joint Research Center has convened a Workshop aimed at ‘Promotion of Technical Harmonization of Risk-Based Decision Making.’ The Workshop’s Guideline for Experts ¹ defines the general role for a Generic Standard by noting:

“It is strongly believed that consideration of risk would be greatly facilitated by an internationally accepted generic "standard" for risk-based decision making. Furthermore, harmonized terminologies, methods and data will greatly increase the general acceptability of risk measures and the potential benefit of cross comparison of risk assessment results.”

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This paper discusses and analyzes the origin and nature of the OECD's CARAT for risk assessment processes and why it well serves as the basis for the Generic Standard proposed by the program committee of the Workshop. It is the authors' belief that the CARAT model will satisfy the Workshop's objective of the "development of a comprehensive set of standards that could be used for application to specific risk assessment studies in different industries."

III Nature of the proposed Generic Standard.

The steering group of EC-JRC International Workshop on "Promotion of Technical Harmonization on Risk-Based Decision Making" has tentatively adopted a basic terminology and structure for a Generic Risk Assessment Standard as outlined in Table 1 and Appendix I of the Guideline for invited experts.² It is believed that this Generic Standard is flexible enough to serve as a basis for developing a generic risk assessment standard common to diverse industrial sectors, such as chemical process plants, operation of hydro dams, transportation of people/goods by a variety of vehicles, operation of nuclear plants, production in the food industry, and other similar technical areas.³

The proposed Generic Standard is acknowledged⁴ to be a generalized version of a risk assessment process model developed as the basis for an OECD project aimed at developing a Risk Assessment Dictionary/Thesaurus (Thesaurus) that focused on one specific technical area: accidental releases of chemicals from fixed installations.

The use and further development of this generic risk assessment standard in the present context will be promoted by understanding the OECD Thesaurus's origins. It is important to recognize that there are important conceptual differences between use of the Standard in the context of the OECD project and its contemplated generic use in diverse technical areas as projected in the current EC-JRC project.⁵

IV Origin, objectives and present status of the OECD major accident risk assessment process Dictionary/Thesaurus effort.

At its September 1995 meeting, the OECD Expert Group on Chemical Accidents (now the OECD Working Group on Chemical Accidents), acting on the recommendation of the July 1995 OECD Workshop on Risk Assessment and Risk Communication in the Context of Accident Prevention, Preparedness and Response,⁶ undertook a project that called for the development of a Risk Assessment Dictionary/Thesaurus (Thesaurus) in the context of accidental releases of chemicals from fixed installations.

A multi-national Steering Group was set up by the OECD Expert Group on Chemical Accidents to execute the project. This group met several times in the intervening years for the purpose of establishing the approach, format and content of the Thesaurus and also to test its usefulness and practicality. Early on, it was decided that the Thesaurus should be a computer-based facility available on the Internet.

The initial emphasis of the Thesaurus was on capturing and communicating different expert's interpretation of the risk assessment mandates embodied in various laws, regulations and guidelines. More recently, development work has also focused on the Thesaurus's ability to capture the intended meaning of definitions related to risk assessment as well as the scope, methodology and assumptions associated with a risk assessment of specific processes. Papers discussing application of the Thesaurus in regard to laws, regulations and specific risk assessment cases have been presented at several technical meetings.^{7,8,9,10,11,12}

After a series of successful system tests,¹³ custodianship of the system was transferred from the developers at the Wharton School's Risk Management and Decision Processes Center of the University of Pennsylvania¹⁴ to the National Institute of Public Health and the Environment (RIVM) in the Netherlands. Recently, OECD re-named the system "CARAT," an acronym for the "Chemical Accident Risk Assessment Thesaurus". CARAT can now be accessed on the Internet at:

<http://www.oecd.org/ehs/carat/>

The online system contains a complete explanation of the design and structure of the hierarchy, as well as explanation for users on how to retrieve useful information from the system. The CARAT has five different search facilities that can be used to retrieve information from the system. One facility searches CARAT for laws/regulations, specific risk assessment cases (SRA), and risk assessment guidance documents (RAG). Another facility searches for the definitions of terms related to risk assessment processes. A third query tool is the "Comparison" facility that allows the user to compare CARAT entries of laws/regulations, SRA, RAG, or definitions, in any combination in regard to their selection of hierarchical features and descriptors. Many find this feature the most powerful and interesting feature of the CARAT, and its *raison d'être*.

The remaining two tools perform searches by identifying entries that contain either certain combinations of hierarchical features, or of descriptor details. The later is a type of "keyword" search facility that is useful in identifying entries that selected certain descriptors. Both types can be conducted in Boolean 'and/or' mode.

V Development of the operational structure of the risk assessment process used as a basis for developing CARAT.

Early in the development work on the OECD Thesaurus project, an analysis of the way various technical groups in different countries categorize and describe the risk assessment process was completed.¹⁵ Particular attention was paid to risk assessment considerations from six diverse organizations:

- Institution of Chemical Engineers¹⁶
- Exposure Assessment Task Group of the USA Chemical Manufacturers Association¹⁷
- Center for Chemical Process Safety of the American Institute of Chemical Engineers¹⁸
- United States Council on Environmental Quality, Executive Office of the President¹⁹
- OECD Workshop on Risk Assessment and Risk Communication in the Context of Accident Prevention, Preparedness and Response, Paris, July, 1995²⁰
- Risk Assessment Council, USA Environmental Protection Agency, Washington DC, November, 1991²¹

Based on this study, it was concluded that, for the most part, risk assessments in all technical areas covered a minimum set of similar process steps. Differences observed in the execution or description of the risk assessment process for different hazards in different technical areas and various countries reflect differences in the availability of technical risk assessment tools, differences in the focus of attention in various technical areas, overlaid with cultural and historical factors.

These differences manifest themselves in two major ways:^{22,23}

- 1) In the choices made by practitioners and legal entities as to which specific operational steps of the total set of risk assessment process steps are addressed and which are to be left unaddressed, and, if addressed, which are to be treated quantitatively rather than qualitatively.

- 2) The manner in which practitioners and legal entities chose to define, group or name a given set of operational steps.

These differences are evident especially in the terminology used to describe similar operations. For example the Center for Chemical Process Safety's "*Guidelines for Hazard Evaluation Procedures*" states that "(a)t one time or another, all of the terms listed in Table 1.1 have been used for hazard evaluation studies."²⁴ Table 1.1 of this book mentions the following list of terms:

- Process Hazard(s) Analysis
- Process Hazard(s) Review
- Process Safety Review
- Process Risk Review
- Predictive Hazard Evaluation
- Hazard Assessment
- Process Risk Survey
- Hazard Study

In addition, one should also add the term 'hazard analysis' to this list, because the book's Glossary gives the following definitions of 'hazard analysis' and 'hazard evaluation':

"Hazard analysis: See hazard evaluation.

Hazard evaluation: The analysis of the significance of hazardous situations associated with a process or activity. Uses qualitative techniques to pinpoint weaknesses in the design or operation of facilities that could lead to accidents."²⁵

Thus, in this recognized reference work, 'hazard analysis' and 'hazard evaluation' are synonymous with all the other terms listed in Table 1.1.

This confusion in risk assessment terminology is compounded when different practitioners use the same label to cover seemingly different intended meanings or operational steps. For example, the well-known British reference work, *Nomenclature for Hazard and Risk Assessment in the Process Industries*,²⁶ does not define hazard evaluation but does define hazard analysis:

"hazard analysis ... the identification of undesired events that lead to the materialization of a hazard; the analysis of the mechanisms by which these undesired events could occur and usually the estimation of the extent, magnitude and likelihood of any harmful effects."²⁷

Thus, the *Nomenclature's* definition of 'hazard analysis' includes the operation "estimation of ...likelihood", a notion usually associated with the term 'risk,' a concept absent from the Center for Chemical Process Safety's "*Guidelines for Hazard Evaluation Procedures*" definition.

VI Assumptions for the hierarchical structure used in CARAT.

After these literature reviews were completed, the project leaders consulted with risk analysts who specialize in a range of hazards to a variety of subjects: people, ecological systems, and property. The hazard sources included toxic chemicals, especially carcinogens; reactive chemicals; and flammable and explosive chemicals. With this background, the project leaders approached design of CARAT making the following assumptions:

1. Risk assessment is a process accomplished by carrying out a series of distinct steps.
2. These steps can be decomposed and hierarchically organized to as fine an operational level as is needed to collect and communicate information on the nature of a specific risk assessment with the desired level of understanding.
3. The elements of the hierarchy can be defined generically enough to be inclusive of most approaches to risk assessment.
4. Each operational step in the risk assessment process should be addressed in some fashion regardless of whether addressing it is either an explicit operation requiring great technical sophistication or an implicit assumption requiring virtually no affirmative action.

By and large, the success in capturing and communicating a wide range of risk assessment processes by CARAT indicates that these assumptions are valid.

Using a consultative process, decisions were taken on the structure of the hierarchical system for capturing inputs and furnishing outputs. The broad structure (Elements and Sub-Elements) was designed, to the extent practicable, to capture and mirror 'consensus' features used by different risk cultures in executing the risk assessment process. The fine structure (Categories and Descriptors) was designed with an eye toward the intended application of accidental chemical releases from chemical facilities.

Particular attention was paid to avoiding use of "terms of art" such as dose, exposure, risk, etc., for obvious reasons. This of course leads to increased verbosity that must be endured though hopefully minimized. One cannot convey clear meaning using words whose meaning is equivocal.

VII The hierarchical risk assessment structure used in CARAT.

The risk assessment system employed as the basis for CARAT is organized hierarchically. At the top level, there are four broad Generic Elements:²⁸

Generic Element I: Identification of sources with the potential to cause undesired outcomes to subjects of concern that are the focus of the estimation of likelihood.

Generic Element II: Identification of possible sequences of events leading to loss of containment of the potential to cause undesired outcomes to a subject of concern resulting in its entry into a domain of the ecosystem. Estimation of possible distributions of both the released potential and the subjects of concern over time periods within compartments delimited by specified boundaries or end-points.

Generic Element III: Identification and description of how the specified undesired outcome is related to the intensity, time, and mode of contact of a specified potential to cause the undesired outcome to the subject(s) of concern.

Generic Element IV: Consists of two parts:

Part A: Identification of the methods for estimating and expressing the likelihood of a specified effect and describing the quality of such estimates.

Part B: Identification of the basis for comparing derived estimates of likelihood to specified guidelines and describing the dependence of these estimates on explicitly specified alternative assumptions.

Generic Elements have a varying number of Sub-elements, and each Sub-element has one corresponding Term. However, each Term is broken into any number of Categories containing a set of Descriptors which make up the lowest level of the system. Generic Element IV in CARAT has two sub-parts; the implications of which will be addressed later.

The terminology used to describe these hierarchical levels is as follows:

- Element:*** A group of related, operationally defined, general concepts.
- Sub-Element:*** One or more operations, methodologies, actions or process steps that encompass a phase of the generic element in the risk assessment process.
- Term:*** A single concept that is the subject of the action defined by the sub-element.
- Category:*** Examples that give general operational meaning to a concept and contain a set of related Descriptors applicable to the technology area in question.
- Descriptor:*** Examples that give specific operational meaning to a Category.

While the specific system presently embodied in CARAT's Categories and Descriptors was developed using terminology appropriate for risk assessment of accidental releases of chemicals from fixed facilities, it appears that the underlying structure and system (Elements and Sub-elements) are applicable to the assessment of risk in almost all areas.

It should be stressed that a data entry client's ability to express intended meaning is not constrained by the absence in the hierarchy of a desired preexisting Category or Descriptor. The Categories and Descriptors in CARAT are only a set of examples included because they are most likely to cover common usage in a particular technical area. Clients can create their own Categories and Descriptors as required to capture their intended meaning and to convey their understanding of their entry. The CARAT computer system is able to capture such new entries. Over time, multiple entries of a new Category or Descriptor can be incorporated into revised versions of the CARAT and unused ones can be dropped.

The number of Sub-elements and their Terms, Categories of Descriptors and Descriptors reflect both logic and system needs. They are established to promote ease and effectiveness in collecting the information needed to capture the intended meaning of the person submitting an item and then conveying this meaning to users searching the system.

CARAT also contains provisions for collecting additional information about entries made into the system, which vastly increases the richness of its content. For example when a new entry is made into the system, appropriate requests are made for information on pertinent references as to the origin or nature of the entry. Similarly, in making an entry of say a specific risk assessment, if the person making the entry indicates that they used a "specific method of estimating likelihood", the system provides for including references to the "tool" (methodology) they employed. Likewise, if the party making the entry selects "acute injuries" to people as an "undesired outcome" to be estimated in their risk assessment, the party can provide references to the "criteria" used to define "injured people." Additionally, the system allows comments to be included with all selections to further explain or amplify the client's choice.

Further discussion of the gross hierarchical structure of CARAT is given in Appendix I and the complete structure of the system as applied to the risk assessment of releases of chemicals from fixed facilities is given in Appendix II. Additional description about CARAT terminology and procedures for entering new items or for searching the system are found at CARAT's Internet address.²⁹

VIII Test of the functionality of CARAT in regard to capturing and communicating a specific risk assessment.

As noted, CARAT has provisions for entering specific risk assessments related to major chemical accidents in fixed facilities, though until now the main thrust of CARAT has been the risk assessment features of laws, regulations, and guidelines.

A paper dealing with the entry of a quantitative risk assessment (QRA) done on a chlorine unloading facility into an earlier version of the CARAT system concludes:

“The OECD Dictionary/Thesaurus [a.k.a. CARAT] provides a logical description of the example QRA, and documents the assumptions used to do the analysis. The description of the QRA clearly illustrates a sound and logical risk management process and clearly describes the basis for decision making.”³⁰

The paper also points out a number of areas dealing largely with procedural difficulties in entering and retrieving reports. Most of these problems have been addressed in subsequent versions of the CARAT.

Of particular interest to this workshop is that the client chose to use Element III, “Mode of contact between the potential to cause the undesired outcome and the subject of concern,” to convey vital information in regard to the basis used for arriving at the injury/death outcomes of various chlorine release scenarios. The following excerpt of Table 3 from the reference illustrates how Element III details the "mode of contact" and the "undesired outcome."

Table 3: Sub-elements and Descriptor for Element III for Example QRA²⁷

Sub-element		Descriptors	
i	Type of Contact	People	Inhalation
ii	Basis for relationship used to predict undesired outcome	People	Human epidemiological data, animal data, weighted combination of data (Withers and Lees, 1985)
iii	Measurement units of the potential specified	Concentration of substance over specified time	Dose-response relationship over 0-60 minute time period based on Withers and Lees (1985) probit
iv	Measurement units of undesired outcome	Total number of outcome events in the specified population	Estimated number of deaths; likelihood of fatality at a particular location

IX Recommendations on the structure and development of a proposed generic risk assessment process standard.

The authors arrive at the following recommendations in regard to the proposed Generic Risk Assessment Standard:

1. The concept of developing a generic risk assessment standard that serves as a template for technical area specific standards is a desirable and feasible approach towards meeting the strategic goal of promoting harmonization of the risk assessment process among diverse technical areas.
2. The workshop’s proposal to fashion a Generic Standard following the structure utilized in the OECD CARAT system will work well provided the following steps are taken:

- All of the Elements, Sub-elements and Terms in the CARAT system should be retained and used to construct the basic hierarchy of all specific risk assessment standards. The authors believe that any gains in simplification from the contemplated elimination of explicit dose/response considerations (CARAT's Element III ³¹) from the Generic Standard will be more than offset by difficulties in achieving harmonization of risk assessment standards among diverse technical areas.
 - CARAT Generic Element IV, consisting of the two parts A and B, should be divided into two separate elements in the proposed Generic Standard. This will clarify that the operational steps embodied in CARAT's Generic Elements I through Generic Element IV Part A constitute what is generally recognized as "risk analysis." The additional operational step embodied in Generic Element IV Part B adds the notion generally recognized as "risk assessment." Such a separation will simplify and clarify the structure of the proposed Generic Standard.
 - The Categories and Descriptors used in CARAT were designed for application to chemical process industries. They can not be incorporated in the Generic Risk Assessment Standard as such because, by their nature, Categories and Descriptors refer to specific areas of technology. On the other hand, the Generic Standard should specify the need for inclusion of appropriate Categories and Descriptors in the Standards for each specific technical area. Since no standard can be completely predictive of future needs, provision for easy addition of appropriate Categories and Descriptors when lacking must be made.
3. When the Generic Standard is extended to specific technical areas, the Generic Standard should require provision for collecting information on specific entries, as follows:
 - Information about the party making the entry (name, organization, country, etc.).
 - Specific document reference for each selection of descriptor, criteria and tools.
 4. The requirement for computer access, search, and reporting features of CARAT should be incorporated in the Generic Standard. Public access to each technical area generic standard is facilitated by Internet access.

For the purpose of discussion, a generic risk assessment that incorporates the suggestions made above will be referred to as the proposed Generic Standard.

X Evaluation of the proposed generic risk assessment process standard.

This workshop's "Guideline for Experts" document describes the ideal set of attributes for a generic risk assessment process standard as follows:

"The generic standard for risk-based decision making to be developed is intended

- *to assist risk assessors and risk decision-makers in standardizing assessments of the risk to human health and the environment in the planning, reporting and review phases,*
- *to enable this user group easy cross-comparisons, completeness and consistency checks of specific risk assessments,*
- *to be at a fundamental level, rather than being industry or application specific,*
- *to follow a "minimum approach", i.e. the elements listed in the standard are the ones at least to be addressed,*

but is

- *not directed towards standardizing the safety goals or risk criteria, but rather the ways how to assure compliance with them,*
- *not directed towards standardizing the tools to perform risk assessment, but rather its underlying process,*
- *not intended to be an algorithmic standard ("cookbook"), but rather a flexible standard which serves as to check completeness & adequacy of a risk assessment.*

In particular, this generic standard is intended to be:

- *Transparent*
- *Coherent*
- *Consistent*
- *Complete*
- *Comprehensive*
- *Impartial*
- *Uniform*
- *Balanced*
- *Defensible*
- *Sustainable*
- *Flexible*
- *Accompanied by suitable and sufficient guidance."*

The authors of this paper believe that a reader's comparison of the attributes of a Generic Risk Assessment Standard arrived at by the modifications suggested above against these desired Guideline attributes will show it to be an excellent candidate for the EC –JRC project's Generic Risk Assessment process Standard.

In order to validate this belief, participants at this workshop and other readers are asked to provide the authors with their opinions and comments by e-mail to either christian.kirchsteiger@jrc.it or Rosenthal@csb.gov prior to the meeting with copies to A.J. Ignatowski at alhzcm@aol.com.

XI Conclusions on the suitability of the proposed generic risk assessment process standard as basis for different industry specific standards and risk assessment studies.

The authors arrive at the following conclusions regarding the proposed Generic Risk Assessment Standard in comparison to the above list of attributes of the ideal generic standard:

1. The CARAT model in its basic structure of Elements, Sub-elements and Terms well serves as the basis of the Generic Standard that can be adapted for a broad spectrum of situations for risk-based decision making.
2. The CARAT model at the lower levels of its hierarchy, namely, Categories and Descriptor, serves as an excellent means of expressing the requirements for specific technical areas of risk assessment.
3. The additional technical features of CARAT, namely, the ability to capture reference information, and the specification of criteria and tools, enhance the richness of specific risk assessment entries.

4. The several query features of the CARAT system allow interested parties to extract the structural features of individual approaches to risk assessment in the various technical areas. In particular, the Comparison report facility is an exquisite tool for comparing the approaches to risk assessment at an operational level, having removed all uses of 'terms of art' in the data entry process.
5. Finally, the overall design of the CARAT allows great flexibility in a number of ways, including the actual text of the hierarchical elements and the number of hierarchical elements at any level. Most importantly, the structure of Categories and Descriptors allow their modification to meet the needs of any technology area.

Appendix I

Gross features of the hierarchical structure used in CARAT.

The gross features of the hierarchical structure used in CARAT are shown in Figure 1. At the most abstract level, the risk assessment process is decomposed into four Elements that are described in operational language, i.e., no use of ‘terms of art.’

Figure 1

Four Generic Elements

Generic Element I: Identification of sources with the potential to cause undesired outcomes to subjects of concern that are the focus of the estimation of likelihood.

Generic Element II: Identification of possible sequences of events leading to loss of containment of the potential to cause undesired outcomes to a subject of concern resulting in its entry into a domain of the ecosystem. Estimation of possible distributions of both the released potential and the subjects of concern over time periods within compartments delimited by specified boundaries or end-points.

Generic Element III: Identification and description of how the specified undesired outcome is related to the intensity, time, and mode of contact of a specified potential to cause the undesired outcome to the subject(s) of concern.

Generic Element IV: Consists of two parts:

Part A: Identification of the methods for estimating and expressing the likelihood of a specified effect and describing the quality of such estimates.

Part B: Identification of the basis for comparing derived estimates of likelihood to specified guidelines and describing the dependence of these estimates on explicitly specified alternative assumptions.

Each of the Elements is decomposed into its component operational process steps, referred to as Sub-elements. Corresponding to each Sub-element is a ‘Term’ that describes the ‘thing’ that is being operated on in the process described in the Sub-element. Figure 2 illustrates these features for Generic Element I.

Figure 2.

Sub-elements and Terms Corresponding to Element I

Element I

Sub-element I i: Identification of sources with the potential to cause undesired outcomes to subjects of concern

Term I i: Sources with the potential to cause undesired outcomes

Sub-element I ii: Identification subjects of concern

Term I ii: Subjects of concern

Sub-element I iii: Identification undesired outcomes to subjects of concern

Term I iii: Undesired outcomes to subjects of concern

Groups of Descriptors called Categories are associated with each Term. Descriptors allow the person entering an item to describe the operation associated with ultimate specificity. Figure 3 shows the Categories associated with Sub-element II and the corresponding Term.

Figure 3
Categories Corresponding to the Term of Sub-element II

Term: Subjects of concern

Categories:

- People
- Ecosystems/environment
- Cultural assets
- Property and physical systems
- Facilities
- Other subjects of concern

In Figure 4, one can trace the following specific path through the hierarchical structure. Element I deals with the operation of “identifying sources of the potential to cause undesired outcomes to subjects of concern”. This is decomposed into three Sub-elements (operations), one of which is “Identification of subjects of concern”. The Term for this Sub-element is “Subjects of concern”. Associated with this Sub-element are Categories of descriptors such as ‘people’, ‘property’, ‘ecosystems’ etc. Each category contains specific Descriptors. For example, the Category ‘people’ contains Descriptors such as ‘residents,’ ‘workers,’ ‘pregnant women,’ etc. The system also contains provisions for entering additional descriptors in a Category, or indeed new Categories if the suggested ones do not directly capture the intended meaning in a given situation.

Figure 4
Hierarchical Path for Subjects of Concern

Element I Identification of sources with the potential to cause undesired outcomes to subjects of concern that is the focus of the estimation of likelihood.

Sub-element ii: Identification subjects of concern

Term: Subjects of concern

Categories:

People

Descriptors:

- Residents
- Sensitive resident populations
- Pregnant residents
- Transient people
- Workers at facilities containing a source with potential to cause undesired outcomes
- Trans-boundary populations
- Undefined people

Appendix II Complete Hierarchical Structure of CARAT

(NOTE: The Arabic numbers at the left of each hierarchical feature refers to the database identification of the feature. For example, 1,1,1,3,2 refers to the second Descriptor in the third Category of the first Term of the first Sub-element of the first Element.)

Pre-Assessment

Identification of aspects of the risk assessment process that are not captured by Generic Elements I to IV, and are judged to precede them, e.g., scope, or purpose of the risk assessment

Element I

- 1 Identification of sources with the potential to cause undesired outcomes to subjects of concern that are the focus of the estimation of likelihood
 - 11 Identification of sources with the potential to cause undesired outcomes to subjects of concern
 - 11 1 Sources with the potential to cause undesired outcomes
 - 11 1 1 Substances
 - 11 1 1 1 **Explosive**
 - 11 1 1 2 **Flammable**
 - 11 1 1 3 **Reactive**
 - 11 1 1 4 **Oxidizing**
 - 11 1 1 5 **Toxic to humans**
 - 11 1 1 6 **Toxic to ecosystems**
 - 11 1 1 7 **Carcinogenic substance**
 - 11 1 1 8 **Teratogenic substance**
 - 11 1 1 U **Undefined substance**
 - 11 1 2 Energy
 - 11 1 2 1 **Pressure**
 - 11 1 2 2 **Thermal flux**
 - 11 1 2 3 **Radiation**
 - 11 1 2 4 **Dynamic energy**
 - 11 1 2 U **Undefined form of energy**
 - 11 1 3 Physical situations
 - 11 1 3 1 **Systems containing flammable substances**
 - 11 1 3 2 **Systems containing reactive chemicals**
 - 11 1 3 3 **Systems containing regulated chemicals**
 - 11 1 3 4 **Facilities prone to natural disasters**
 - 11 1 3 U **Undefined physical situation**
 - 11 1 4 Legally specified sources
 - 11 1 4 1 **Listed substances**
 - 11 1 4 U **Undefined legal source**
 - 11 1 5 Other sources
 - 11 1 5 U **Undefined category of source**
- 12 Identification subjects of concern
 - 12 1 Subjects of concern
 - 12 1 1 People
 - 12 1 1 1 **Residents**
 - 12 1 1 2 **Sensitive resident populations**
 - 12 1 1 3 **Pregnant residents**
 - 12 1 1 4 **Transient people**
 - 12 1 1 5 **Workers at facilities containing a source with potential to cause undesired outcomes**
 - 12 1 1 6 **Trans-boundary populations**
 - 12 1 1 U **Undefined people**

12	1	2	Ecosystems/environment
12	1	2	1 Aquatic habitats
12	1	2	2 Terrestrial habitats
12	1	2	3 Underground water
12	1	2	4 Endangered species
12	1	2	5 International waters or rivers
12	1	2	U Undefined subject of the ecosystem/environment
12	1	3	Cultural assets
12	1	3	1 Cemeteries
12	1	3	2 Historical sites
12	1	3	3 Sacred ground
12	1	3	U Undefined cultural asset
12	1	4	Property and physical systems
12	1	4	1 Residential property
12	1	4	2 Commercial property
12	1	4	3 Civic property
12	1	4	4 Communication systems
12	1	4	5 Transportation systems
12	1	4	6 Drinking water supply systems
12	1	4	7 Power transmission systems
12	1	4	U Undefined property or physical system
12	1	5	Facilities
12	1	5	1 Hospitals
12	1	5	2 Schools
12	1	5	3 Neighboring facilities containing a source of potential to cause undesired outcomes
12	1	5	4 Places of worship
12	1	5	5 Prisons
12	1	5	U Undefined facility
12	1	6	Other subjects of concern
12	1	6	U Undefined subject of concern
13			Identification undesired outcomes to subjects of concern
13	1		Undesired outcomes to subjects of concern
13	1	1	Undesired outcomes for people
13	1	1	1 Death
13	1	1	2 Acute injury
13	1	1	3 Acute illness
13	1	1	4 Chronic illness
13	1	1	5 Cancer
13	1	1	6 Birth defects
13	1	1	7 Irreversible health effect
13	1	1	8 Hospital treatment
13	1	1	9 Evacuation/confinement
13	1	1	10 Damage to residence
13	1	1	11 Economic loss
13	1	1	12 Need to shelter-in-place
13	1	1	13 Anxiety caused by an event associated with undesired outcomes
13	1	1	U Undefined undesired outcome for people
13	1	2	Undesired outcomes for ecosystems/environment
13	1	2	1 Damage to aquatic habitat
13	1	2	2 Damage to terrestrial habitat
13	1	2	3 Damage to underground water
13	1	2	4 Damage to international body of water or river
13	1	2	U Undefined undesired outcome for ecosystems/environment

13	1	3	Undesired outcomes for cultural assets
13	1	3	1 Damage to cultural assets
13	1	3	2 Damage to historical sites
13	1	3	3 Desecration of sacred ground
13	1	3	U Undefined undesired outcome for cultural asset
13	1	4	Undesired outcomes for society
13	1	4	1 A release of a source of sufficient magnitude to cause an undesired outcome
13	1	4	2 Anxiety caused by a foreseeable event associated with undesired outcome
13	1	4	U Undefined undesired outcome for society
13	1	5	Undesired outcomes for facilities having the release
13	1	5	1 Injury to people within a facility
13	1	5	2 Death of workers within a facility
13	1	5	3 Property damage
13	1	5	4 Business interruption
13	1	5	5 Loss of good will
13	1	5	6 Legal sanction
13	1	5	U Undefined undesired outcome for facilities
13	1	6	Undesired outcomes for property
13	1	6	1 Damage to residential property
13	1	6	2 Damage to commercial property
13	1	6	3 Damage to civic property
13	1	6	4 Interruption of communication system
13	1	6	5 Interruption of transportation system
13	1	6	6 Interruption of drinking water supply
13	1	6	7 Interruption of power system
13	1	6	U Undefined undesired outcome for property
13	1	7	Undesired outcomes for other classes of subjects
13	1	7	U Undefined undesired outcome for other classes of subjects

Element II

- 2 Identification of sequences of events that can lead to loss of containment of the potential to cause undesired outcomes and its entry into a domain defined by specified boundaries. Identification of the basis for estimating the distribution of both the released potential and the subjects of concern within this domain
- 21 Identification of the basis for generating sequences of events leading to a loss of containment resulting in the entry of the potential to cause undesired outcomes into a domain that may be occupied by a subject of concern
 - 21 1 Basis for generating sequences of events leading to loss of containment resulting in the entry of the potential to cause undesired outcomes into a domain that may be occupied by a subject of concern
 - 21 1 1 Sequence of events based on past events or experience
 - 21 1 1 1 **Insurance or industry records**
 - 21 1 1 2 **Professional judgment**
 - 21 1 1 3 **Sabotage potential**
 - 21 1 1 4 **Technical guidance**
 - 21 1 1 U **Undefined past event or experience**

21	1	2	Sequence of events based on technical analysis
21	1	2	1 Failure Mode and Effect Analysis
21	1	2	2 Fault-tree analysis for sequence of events
21	1	2	3 Event-tree analysis for sequence of events
21	1	2	4 HazOP
21	1	2	5 What If
21	1	2	6 Check list
21	1	2	7 Task analysis
21	1	2	U Undefined technical analysis for generating sequence of events
21	1	3	Sequence of events legally determined
21	1	3	1 "Worst case" sequence of events
21	1	3	2 "Most credible worst case"
21	1	3	U Undefined sequence of events legally determined
21	1	4	Other sequence of events categories
21	1	4	U Undefined category of event sequence
22			Identification of the basis for estimating distributions of the released potential within domains of interest
22	1		Basis for estimating distribution of the released potential within domains of interest
22	1	1	Distributions based on real-time monitoring
22	1	1	1 Personal exposure measurement
22	1	1	2 Continuous instrumental monitoring
22	1	1	3 Observation from aircraft
22	1	1	U Undefined real-time monitoring
22	1	2	Distributions based on technical analysis
22	1	2	1 Event-tree analysis for distribution of the release
22	1	2	2 TNO Yellow Book
22	1	2	3 ARCHIE model
22	1	2	4 SAFETI model
22	1	2	5 BP CIRRUS
22	1	2	6 U.S. EPA RMP Offsite Consequence Analysis Guidance for distribution
22	1	2	7 Thermal flux modeling
22	1	2	8 Overpressure modeling
22	1	2	9 Biochain modeling
22	1	2	U Undefined technical analysis for estimating distribution
22	1	3	Distributions legally determined
22	1	3	1 "Worst case" distribution of the potential to cause an undesired outcome
22	1	3	2 Use of specific technical models
22	1	3	3 Look-up table for distribution of subjects of concern
22	1	3	U Undefined legally determined approach for estimating distribution
22	1	4	Other approaches to estimation of distributions
22	1	4	U Undefined approach to estimation of distribution
23			Identification of the basis for estimating distributions of subjects of concern within domains of interest
23	1		Basis for estimating distribution of the subjects of concern within domains of interest
23	1	1	Real-time monitoring
23	1	1	1 Surveillance cameras
23	1	1	2 Traffic monitoring
23	1	1	3 Satellite systems
23	1	1	U Undefined type of real-time monitoring

23	1	2	Historical data
23	1	2	1 Census data
23	1	2	2 Prospective surveys
23	1	2	3 Retrospective surveys
23	1	2	U Undefined type of historical data for estimating distribution of subjects
23	1	3	Distributions legally determined
23	1	3	1 "Worst case" distribution of the subject of concern
23	1	3	2 Look-up table for boundaries
23	1	3	U Undefined type of legally determined approach for estimating distribution of subjects
23	1	4	Other approaches to estimation of distribution of subjects
23	1	4	U Undefined approach for estimating distribution of subjects
24			Identification of the basis for establishing boundaries that delimit estimates of the distribution of the released potential
24	1		Basis for defining the boundaries that delimit the distribution of the released potential
24	1	1	Boundaries or end-points based on technical analysis
24	1	1	1 Threshold Limit Value (TLV) for boundary
24	1	1	2 Maximum Allowable Concentration (MAC) for boundary
24	1	1	3 Maximum Contaminant Level (MCL) for boundary
24	1	1	4 Lethal Dose for 50 percent population (LD50 or LC50)
24	1	1	5 No Observed Effect Level (NOEL)
24	1	1	6 Emergency Response Planning Guide (ERPG)
24	1	1	7 Overpressure of 1 pound per square inch
24	1	1	8 Radiant energy flux of 5 kW/M2/40 seconds
24	1	1	9 U.S. EPA RMP Offsite Consequence Analysis Guidance for boundaries
24	1	1	U Undefined technically derived endpoint
24	1	2	Boundaries or end-points legally determined
24	1	2	1 National or political boundary
24	1	2	2 Look-up table for distribution of the potential to cause undesired outcomes
24	1	2	U Undefined legally determined boundary
24	1	3	Other approaches to setting boundaries or end-points
24	1	3	1 Odor threshold
24	1	3	U Undefined approach for setting boundary or endpoint

Element III

3			Identification and description of how the specified undesired outcome is related to the intensity, time and mode of contact of a specified potential to cause the undesired outcome to the subject of concern
31			Identification of the way the specified potential to cause the undesired outcome makes contact with to the subject of concern to cause the specified undesired outcome
31	1		Mode of contact between the potential to cause the undesired outcome and the subject of concern
31	1	1	Mode of contact between the potential to cause undesired outcomes and people
31	1	1	1 Inhalation
31	1	1	2 Skin absorption
31	1	1	3 Ingestion
31	1	1	4 Pressure wave contact with people
31	1	1	5 Flying object contact with people
31	1	1	6 Radiant flux exposure to people
31	1	1	U Undefined mode of contact with people

31	1	2		Mode of contact between the potential to cause undesired outcomes and ecosystems/environment
31	1	2	1	Ingestion/absorption by living organisms
31	1	2	2	Deposition into water systems
31	1	2	3	Dispersion into the environment
31	1	2	U	Undefined mode of contact with the ecosystem/environment
31	1	3		Mode of contact between the potential to cause undesired outcomes and cultural assets
31	1	3	1	Surface contact with cultural assets
31	1	3	2	Pressure wave contact with cultural assets
31	1	3	3	Flying object contact with cultural assets
31	1	3	4	Radiant flux exposure to cultural assets
31	1	3	U	Undefined mode of contact with cultural assets
31	1	4		Mode of contact between the potential to cause undesired outcomes and property and public infrastructure systems
31	1	4	1	Surface contact with property
31	1	4	2	Pressure wave contact with property
31	1	4	3	Flying object contact with property
31	1	4	4	Radiant flux exposure to property
31	1	4	U	Undefined mode of contact with property and public infrastructure systems
31	1	5		Mode of contact between the potential to cause undesired outcomes and other classes of subjects of concern
31	1	5	1	Surface contact other subjects of concern
31	1	5	2	Pressure wave contact with other subjects of concern
31	1	5	3	Flying object contact with other classes of subjects
31	1	5	4	Radiant flux exposure to other subjects of concern
31	1	5	U	Undefined mode of contact with other classes of subjects
32				Identification of the basis of the relationship used to predict how the undesired outcome is related to contact with the potential to cause the undesired outcome
32	1			Basis for the relationship used to predict how the specified undesired outcome is related to contacts with the potential to cause the undesired outcome
32	1	1		Relationship to people
32	1	1	1	Human clinical data
32	1	1	2	Human epidemiological data
32	1	1	3	Animal data
32	1	1	4	Experimental data (other) related to people
32	1	1	5	Structure/activity relationships related to people
32	1	1	6	Weighted combination of data
32	1	1	U	Undefined basis for prediction of the relationship to people
32	1	2		Relationship to ecosystems/environment
32	1	2	1	Ecotoxicology studies
32	1	2	2	Ecological field studies
32	1	2	3	Experimental data (other) related to ecosystems
32	1	2	4	Structure/activity relationships related to ecosystems/environment
32	1	2	U	Undefined basis for prediction of the relationship to ecosystems/environment
32	1	3		Relationship to cultural assets
32	1	3	1	Analysis of insurance damage claims against cultural assets
32	1	3	2	Analysis of historical events regarding cultural assets
32	1	3	U	Undefined basis for prediction of the relationship to cultural assets

32	1	4		Relationship to property and public infrastructure systems
32	1	4	1	Analysis of insurance damage claims against property and public infrastructure systems
32	1	4	2	Analysis of historical events regarding property and public infrastructure systems
32	1	4	U	Undefined basis for prediction of the relationship to property and public infrastructure systems
32	1	5		Relationships to other subjects of concern
32	1	5	U	Undefined basis for prediction of the relationship to other subjects of concern
33				Description of the dimensions/measurement units of the potential to cause the undesired outcomes that are used to predict the undesired outcome
33	1			Dimensions/measurement units of the potential used in predicting the undesired outcome
33	1	1		Concentration of the substance with the potential to cause the specified undesired outcome that interacts with the subject over a specified time period
33	1	1	1	ppm over an eight-hour work day
33	1	1	2	mg/m3 for a specified time period
33	1	1	U	Undefined measure of concentration in a time period
33	1	2		Amount of the substance with the potential to cause the specified undesired outcome that interacts with the subject over a specified time period
33	1	2	1	Grams/70 years
33	1	2	U	Undefined quantity of substance in a time period
33	1	3		Overpressure delivered to a subject of concern
33	1	3	1	Grams/cm2
33	1	3	2	Lb./inch2
33	1	3	U	Undefined overpressure measurement
33	1	4		Energy flux delivered to the subject over a specified time period and area
33	1	4	1	KW/M2/40 sec
33	1	4	U	Undefined energy flux measurement
33	1	5		Other measures/dimensions of input potential
33	1	5	U	Undefined input measure/dimension of input potential
34				Description of the dimensions/measurement units used to express the undesired outcome response
34	1			Dimensions/measurement units used to express the predicted undesired outcome
34	1	1		Magnitude of the undesired outcome experienced by the specified individual subject of concern
34	1	1	1	Percentage of skin surface with second degree burn injury
34	1	1	2	Percentage of reduction in respiratory capacity
34	1	1	3	Percentage of structural damage
34	1	1	U	Magnitude of undefined undesired outcome to an individual subject of concern
34	1	2		Number of the undesired outcome events experienced by the specified population of subjects
34	1	2	1	Number of deaths
34	1	2	2	Number of birth defects
34	1	2	3	Number of buildings with a specified degree of structural damage
34	1	2	U	Number of undefined undesired outcome to a specified population of subjects
34	1	3		Frequency of the undesired outcome events experienced by the specified population of subjects
34	1	3	1	Frequency of deaths
34	1	3	2	Frequency of birth defects
34	1	3	3	Ratio of subjects with undesired outcome to those without
34	1	3	U	Frequency of undefined undesired outcome to a specified population of subjects

34	1	4	Likelihood of the undesired outcome given the specified interactions with the potential to cause the undesired outcomes by specified subjects
34	1	4	1 Likelihood of deaths
34	1	4	2 Likelihood of birth defects
34	1	4	3 Likelihood of cancer
34	1	4	U Likelihood of undefined undesired outcome to specified subjects
34	1	5	Other measures of undesired outcomes by specified subjects
34	1	5	U Undefined measures of undesired outcome to specified subjects

Element IV

4			Consists of two parts: Part A: Identification of the methods for estimating and expressing the likelihood of a specified effect and describing the quality of such estimates. Part B: Identification of the basis for comparing derived estimates of likelihood to specified guidelines and describing the dependence of these estimates on explicitly specified assumptions
4 1			Identification of the basis of estimating the likelihood that specified undesired effects will occur, that is, that a specified undesired outcome of a specified magnitude for a specified subject of concern will occur
4 1	1		Method of estimating the likelihood that specified undesired effects will occur
4 1	1	1	Quantitative methods of estimating likelihood
4 1	1	1	1 Specific quantitative method of estimating likelihood
4 1	1	1	2 Quantitative event-tree analysis for estimating likelihood
4 1	1	1	3 Quantitative fault-tree analysis for estimating likelihood
4 1	1	1	4 SAFETI model
4 1	1	1	5 Riskplot
4 1	1	1	6 Plato model
4 1	1	1	U Undefined quantitative method of estimating likelihood
4 1	1	2	Semi-quantitative methods of estimating likelihood
4 1	1	2	1 Specific semi-quantitative method of estimating likelihood
4 1	1	2	U Undefined semi-quantitative method of estimating likelihood
4 1	1	3	Qualitative methods of estimating likelihood
4 1	1	3	1 Specific qualitative method of estimating likelihood
4 1	1	3	2 Qualitative judgment of likelihood based on perception of a facility's character
4 1	1	3	3 Reliance on protection implied by conformance with recognized worker exposure limit
4 1	1	3	U Undefined qualitative method of estimating likelihood
4 1	1	4	Methods of estimating likelihood based on historical data
4 1	1	4	1 Method of estimating likelihood based on extrapolation of historical data
4 1	1	4	U Undefined method of estimating likelihood based on historical data
4 1	1	5	Methods of estimating likelihood based on judgments of the degree of conformance with criteria
4 1	1	5	1 Method of estimating likelihood based on legal criterion
4 1	1	5	2 Method of estimating likelihood based on technical criterion
4 1	1	5	3 Method of estimating likelihood based on `more likely than worst case
4 1	1	5	U Method of estimating likelihood based on conformance with undefined criterion
4 1	1	6	Other approaches for estimation of likelihood
4 1	1	6	U Undefined method of estimating likelihood

42				Identification of the method of expressing the likelihood that specified undesired effects will occur, that is, that a specified undesired outcome of a specified magnitude for a specified subject of concern will occur
42	1			Method of expressing the likelihood that a specified undesired effect will occur
42	1	1		Quantitative expressions
42	1	1	1	Probability
42	1	1	2	Frequency
42	1	1	3	Probability of a specified sequence of events resulting in a specified undesired effect in a specified time period
42	1	1	4	Probability of a specified undesired effect if a specified sequence of events occurs
42	1	1	5	Probability of a specified undesired effect in a specified time period
42	1	1	U	Undefined quantitative expression of likelihood
42	1	2		Semi-quantitative expressions
42	1	2	1	Less than a specified likelihood
42	1	2	2	Greater than a specified likelihood
42	1	2	3	Within a range of likelihoods
42	1	2	U	Undefined semi-quantitative expression of likelihood
42	1	3		Qualitative expressions
42	1	3	1	Acceptable, a qualitative expression
42	1	3	2	Unacceptable, a qualitative expression
42	1	3	3	Negligible
42	1	3	4	High
42	1	3	5	Low
42	1	3	U	Undefined qualitative expression of likelihood
42	1	4		Expressions of likelihood legally defined
42	1	4	1	Imminent and substantial
42	1	4	2	De minimis
42	1	4	3	Acceptable, a legally defined expression
42	1	4	4	Unacceptable, a legally defined expression
42	1	4	5	Tolerable
42	1	4	6	More likely than worst case, likelihood legally defined
42	1	4	U	Undefined expression of likelihood legally defined
42	1	5		Other expressions of likelihood
42	1	5	U	Undefined expression of likelihood
43				Identification of the undesired outcome of a specified magnitude for a specified subject of concern for which the likelihood is being estimated
43	1			Specified undesired effect, that is, the specified undesired outcome of a specified magnitude for a specified subject of concern
43	1	1		Specified member of the population of concern that experiences a specified undesired outcome
43	1	1	1	Average member of the population of concern
43	1	1	2	Average member of a sensitive cohort of the population of concern
43	1	1	3	Average member of a specified cohort of the population of concern
43	1	1	4	Member closest to the release of the potential
43	1	1	5	Member at a specified location
43	1	1	6	Member sheltered in place
43	1	1	U	Undefined member of the population of concern

43	1	2		Specification of a group of N or more subjects of the population of concern that experiences a specified undesired outcome simultaneously
43	1	2	1	N or more average members of the population of concern
43	1	2	2	N or more members of a sensitive cohort of the population of concern
43	1	2	3	N or more specified members of the population of concern
43	1	2	4	N or more members closest to the release of the potential
43	1	2	5	N or more members at a specified location
43	1	2	6	N or more members sheltered in place
43	1	2	U	N or more undefined member of the population of concern
43	1	3		Specification of the undesired outcome resulting from the presence at specified location(s) of the specified potential at concentrations/intensities over time that would be sufficient to cause the undesired outcome for specified subjects of concern
43	1	3	1	Death to residents
43	1	3	2	Damage to residential property
43	1	3	3	Evacuation of schools
43	1	3	U	Undefined undesired outcome for specified subject of concern
43	1	4		Concentrations/intensities of a specified potential over space and time that exceed specified limits which express the magnitude above which undesired outcomes may occur for specified members of the concerned population
43	1	4	1	IDLH (Immediately Dangerous for Life or Health)
43	1	4	2	TLVs (Threshold Limit Values)
43	1	4	3	MACs (Maximum Allowable Concentrations)
43	1	4	4	ERPGs (Emergency Response Planning Guides)
43	1	4	5	Specified overpressure limits
43	1	4	6	Specified radiant energy limits
43	1	4	U	Undefined concentration/intensity limit
43	1	5		Other resulting undesired effects
43	1	5	U	Undefined undesired effect
44				Identification of description of the quality/uncertainty of estimates of likelihood
44	1			Quality/uncertainty of estimates of likelihood
44	1	1		Characterization of estimate
44	1	1	1	Best estimate
44	1	1	2	Conservative estimate (over-estimation)
44	1	1	3	Estimate and its standard deviation
44	1	1	4	Conservative estimate and its confidence limit
44	1	1	5	Monte Carlo distribution of estimates reflecting the uncertainties of data used in the estimation process
44	1	1	U	Undefined means of characterizing quality of estimate
45				Identification of the approach used to compare the estimates of likelihood with relevant standards and guidelines
45	1			Approach used to compare the estimates of likelihood with relevant standards and guidelines
45	1	1		Type of standard or guideline
45	1	1	1	Legal
45	1	1	2	ALARA
45	1	1	3	ALARP
45	1	1	4	Business
45	1	1	5	Company standards
45	1	1	6	Industry standards
45	1	1	7	Social convention
45	1	1	8	Scientific or technical standards
45	1	1	U	Undefined standard or guideline

46				Identification of the metrics or other information needed for comparisons of estimated likelihood against standards or guidelines
46	1			Metrics or other information needed for comparisons of estimated likelihood against standards or guidelines
46	1	1		Comparison metrics
46	1	1	1	The likelihood of a specified undesired outcome for any member in a population of the subjects of concern resulting from a specified series of events
46	1	1	2	The likelihood of a specified undesired outcome for any member in a population of the subjects of concern resulting from a specified series of events if the facility employed all practicable measures to reduce the likelihood and magnitude (ALARP)
46	1	1	3	Plots of the frequency per year of sequences of events (accidents) resulting in N or more fatalities to people as a function of the number of fatalities
46	1	1	4	An estimate of the average number of fatalities per unit time in a population of subjects of concern
46	1	1	5	Contours of areas within which the likelihood of a subject experiencing a specified undesired outcome is greater than an estimated level
46	1	1	6	Contours of areas within which a specified potential may be present at concentrations/intensities over time that exceed a specified limit as a result of a specified series of events
46	1	1	7	The presence of a specified potential at concentrations/intensities over time that exceed a specified limit at a specified location as a result of a specified series of events
46	1	1	8	All undesired outcomes for subjects of concern that could result from sequences of events, using methodology and specifications sequences of events defined in the law, guideline, or standard that is the basis for the comparison
46	1	1	9	An assessment of the adequacy of measures for preventing or containing releases using methodology and specifications for adequacy, using measures of prevention and containment defined in the law, guideline, or standard that is the basis of the comparison
46	1	1	10	An assessment of the adequacy of emergency response measures following the release of the potential to cause the undesired outcome
46	1	1	U	Undefined comparison metric
47				Identification of specified alternative assumptions on the estimates of likelihood
47	1			Specified alternative assumptions whose impacts on likelihood are to be evaluated
47	1	1		Alternative assumptions
47	1	1	1	Assumptions in regard to distributions of subjects of concern in space and time
47	1	1	2	Assumptions in regard to distributions of the potential to cause undesired outcomes in space and time
47	1	1	3	Assumptions in regard to the relationship between undesired outcomes and the degree of interaction of subjects with the potential for undesired outcomes
47	1	1	U	Undefined alternative assumption
48				Description of the impact of specified alternative assumptions on the estimates of likelihood
48	1			Type and form of evaluation of the impact of alternative assumptions on the estimates of likelihood

48	1	1		Evaluation metrics
48	1	1	1	Comparison of calculated likelihoods and their confidence limits using the original assumption and specified alternative assumptions
48	1	1	2	Discussion of the direction and extent of expected changes in the original estimate of likelihood if an alternative assumption is used
48	1	1	3	Discussion of the use of alternative assumptions on the uncertainty of likelihood
48	1	1	4	Discussion of the social and or legal acceptability of the use of an alternative assumption
48	1	1	U	Undefined evaluation metric

Post-Assessment

- 5 Identification of aspects of the risk assessment process that are not captured by Generic Elements I to IV, and are judged to follow them, e.g., the risk assessment/risk management interface

End Notes

¹ EC-JRC International Workshop on “Promotion of Technical Harmonization on Risk-based Decision Making,” Guideline for Invited Experts, Christian Kirchsteiger, section 2.1, page 4, Feb 2000, revision 6.

² Ibid Ref. 1, Table 1, page 13, and Appendix I, p. 29.

³ Ibid Ref. 1, Section 2.2, p. 6.

⁴ Ibid Ref. 1, Section 3.2, p. 12.

⁵ Isadore Rosenthal, Ben Ale and Lyse D. Helsing, “An Outline of the approach being used in developing the OECD Dictionary/ Thesaurus of ‘Risk Assessment’ terminology, *Journal of Hazardous Materials* 61 (1998) 291 – 297.

⁶ “Report of the OECD Workshop on Risk Assessment and Risk Communication in the Context of Accident Prevention, Preparedness and Response”, p. 14, Paris, July 1995.

⁷ Isadore Rosenthal, Ben Ale and Lyse Helsing, “An Outline of the approach being used in developing the OECD Thesaurus-Dictionary of Risk Assessment terminology”, Presented at Warsaw Conference on Trans-Boundary Risks, October 1996.

⁸ Hendershot, D.C. and Schechter, S.J., “Evaluation of a Proposed Thesaurus/Dictionary for Risk Assessment Using an Industrial Quantitative Risk Analysis,” *International Conference and Workshop on Risk Analysis in Process Safety*, October 21-24, 1997, Atlanta, GA, Workshop D: Methodology for Comparing Risk Assessment, American Institute of Chemical Engineers, New York, New York.

⁹ Ignatowski, A.J., Rosenthal, I. and Helsing, L.D., “An Internet Thesaurus/Dictionary for Analyzing Risk Assessment Processes, Laws and Regulations,” *International Conference and Workshop on Risk Analysis in Process Safety*, October 21-24, 1997, Atlanta, GA, Workshop D: Methodology for Comparing Risk Assessment, American Institute of Chemical Engineers, New York, New York.

¹⁰ McNulty, P.J., Barrish, R.A., Antoff, R.C., “Use of the OECD Dictionary Thesaurus to Encode Delaware’s Law for Process Safety”, *International Conference and Workshop on Risk Analysis in Process Safety*, October 21-24, 1997, Atlanta, GA, Workshop D: Methodology for Comparing Risk Assessment, American Institute of Chemical Engineers, New York, New York.

¹¹ Rosenthal, I and Ignatowski, A.J., “*The Nature of Definitions Related to the Risk Assessment Process: Application of the OECD Chemical Accident Risk Assessment Thesaurus to convey the intended meaning of definitions,*” Society for Risk Analysis, SRA Annual Meeting, Atlanta, GA, December 7, 1999.

¹² Ignatowski, A.J. and Rosenthal, I., “*The Chemical Accident Risk Assessment Thesaurus: A Tool for Analyzing and Comparing Diverse Risk Assessment Processes,*” Society for Risk Analysis, SRA Annual Meeting, Atlanta, GA, December 7, 1999.

¹³ Ignatowski, A.J., Report on Version 3 test, OECD Risk Assessment Steering Group Meeting, London, October 1998.

¹⁴ The work done at Wharton was funded by the Corporate Associates of the Risk Center and the OECD Expert Group on Chemical Accidents and in particular by the Chemical Emergency and Preparedness Office of the US EPA and National Institutes for Public Health and the Environment of the Netherlands.

¹⁵ Document 2, second meeting of the OECD Steering Group on Risk Assessment in the Context of Accident Prevention, Emergency Preparedness, and Response, 14-15 February 1996, Washington, DC.

¹⁶ “Nomenclature for Hazard and Risk Assessment in the Process Industries”, D.A. Jones, 2nd Edition, The Institution of Chemical Engineers, Rugby, England, 1985.

¹⁷ “Exposure Glossary”, Exposure Assessment Task Group, Chemical Manufacturers Association, 2501 M Street, NW, Washington. DC 20037, 1995.

¹⁸ “Guidelines for Investigating Chemical Process Incidents”, Center for Chemical Process Safety, American Institute of Chemical Engineers, New York, NY, 1992, Glossary, p. 327.

¹⁹ Cohrssen, J., and Covello, V., “Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks,” United States Council on Environmental Quality, Executive Office of the President, Washington, DC, 1989, Glossary, p. 355.

²⁰ “Report of the OECD Workshop on Risk Assessment and Risk Communication in the Context of Accident Prevention, Preparedness and Response”, p. 14, Paris, July 1995.

²¹ “Guidance For Risk Assessment”, Risk Assessment Council, EPA, Washington, DC, November, 1991.

²² Ibid. Ref. 6, paragraph 22, pp.11 –13.

²³ Rosenthal, I. and Ignatowski, A.J., “The Nature of Definitions Related to the Risk Assessment Process: Application of the OECD Chemical Accident Risk Assessment Thesaurus to convey the intended meaning of definitions”, Society for Risk Analysis, SRA Annual Meeting, Atlanta, GA, December 7,1999, page 2,

²⁴ *Guidelines for Hazard Evaluation Procedures*, American Institute of Chemical Engineers, Center for Chemical Process Safety, 2nd ed. 1992, New York, NY, p. 12.

²⁵ Ibid. p. xxv.

²⁶ *Nomenclature for Hazard and Risk Assessment in the Process Industries*, D.A. Jones Ed., 2nd edition, The Institution of Chemical Engineers, Rugby CV21 3HQ, UK, 1992.

²⁷ Ibid, p.27.

²⁸ The CARAT system provides for the inclusion of a "pre-assessment" element that accomodates aspects that are judged to precede the risk assessment process such as the definition of scope, and a "post-assessment" element that accomodates aspects that may follow the risk assessment process such as risk communication. These are concepts that may be included in the Generic Standard.

²⁹ The address <http://www.oecd.org/ehs/carat/> is the query side of CARAT. The data entry side of CARAT is identification name and password controlled and therefore is not generally viewable.

³⁰ Hendershot, D.C., Schechter, S.J., “Evaluation of a Proposed Thesaurus/Dictionary for Risk Assessment Using an Industrial Quantitative Risk Analysis,” International Conference and Workshop on Risk Analysis in Process Safety. October 21 –24, Atlanta GA. Workshop D: Methodology for Comparing Risk Assessment, New York, American Institute of Chemical Engineers.

³¹ Element III of CARAT reads as follows: Identification and description of how the specified undesired outcome is related to the intensity, time, and mode of contact of a specified potential to cause the undesired outcome to the subject(s) of concern.