Safety Management

Risk Assessment & Hierarchies of Control

Their growing importance to the SH&E profession

By Fred A. Manuele

RISK ASSESSMENT PROVISIONS and hierarchies of control that outline a course of action to be taken to resolve hazard and risk situations are now included in many new and revised safety standards and guidelines. These documents reflect the views of a broad cross-section of SH&E practitioners, and it is likely that future standards will include similar provisions. Therefore, SH&E professionals need to understand risk assessment methodologies and the thought processes encompassed in hierarchies of control. This article discusses:

- recently issued standards and guidelines that require risk assessments and the use of a hierarchy of control;
- the purpose of a hierarchy of control;
- a concept in which hazard identification and analysis, risk assessment and a hierarchy of controls are joined with sound problem-solving methods to create a safety decision hierarchy;
- hazard identification and analysis, and risk assessment methods.

Risk Assessment & Hierarchy of Control Provisions

Following are several examples of standards and guidelines issued in recent years that require risk assessments and the use of a prescribed hierarchy of controls. Other relevant standards are also briefly discussed. These standards and guidelines reflect the work of many SH&E professionals who have agreed that a prescribed and sequential course of action should be undertaken to effectively resolve hazard and risk situations. Although the specifics vary in the cited documents, they all share similar characteristics.

ANSI/ASSE Z244.1-2003

In July 2003, ANSI approved Control of Hazardous Energy: Lockout/Tagout and Alternative Methods. With respect to occupational safety, Z244.1-2003 may have a broader impact than any other safety standard issued in recent years. It will affect a vast number of locations. Section 5.4, which discusses alternative methods of control, is paraphrased here:

> When lockout/tagout is not used for tasks that are routine, repetitive and integral to the production process, or traditional lockout/tagout prohibits the completion of those tasks, an alternative method of control shall be used. Control options shall follow the hierarchy of alternative control implementation shown here. Selection of an alternative control method by the user shall be based on a risk assessment of the machine, equipment or process. The hierarchical control process shall be applied in the following order of preference:
>
> a) eliminate the hazard through design;
>
> b) use engineered safeguards;
>
> c) use warning and alerting techniques;

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d) use administrative controls (e.g., safe work procedures, training);

e) use PPE.

This standard will have a broad impact because it requires a risk assessment *before* an alternative risk control method is selected and also presents a specific hierarchical control methodology.

A hierarchy is any system of actions, things or persons ranked one above the other. For SH&E practitioners, a hierarchy of controls establishes the actions to be considered in an order of effectiveness to resolve unacceptable hazardous situations.

ANSI B11.TR3-2000

In ANSI's identification system, "TR" stands for technical report. TR3 is titled Risk Assessment and Risk Reduction: A Guide to Estimate, Evaluate and Reduce Risks Associated with Machine Tools (AMT). This report was published in November 2000. Section 4 presents an "overview of risk assessment and risk reduction." It proposes that risk assessment methods be used in the design and use of a machine to arrive at a tolerable risk level. The following comments are from Section 8, which discusses risk reduction.

> The risk assessment process yields a level of risk (probability of occurrence of harm and the severity of that harm). The performance and ease of use of protective measures should be appropriate to the desired degree of risk reduction. Protective measures should be applied in the hierarchical order, the major captions for which are as follows.
>
> a) Eliminate the hazard or reduce the risk by design.
>
> b) Apply safeguards.
>
> c) Implement administrative controls or other protective measures.

Although this hierarchy of controls seems briefer than that in ANSI Z244.1, the detail in the standard addresses the same subjects as the lockout/tagout standard. SH&E practitioners should note the difference in perception by the developers of this TR with regard to how the hierarchy of controls should be presented. Also, as ANSI B11 series standards that pertain to the design, construction, care and use of machine tools are updated, the risk assessment and hierarchy of control provisions in TR3 are being incorporated into them.

ANSI/RIA R15.06-1999

This standard, titled Industrial Robots and Robot Systems: Safety Requirements, also includes provisions for risk assessment and the use of a hierarchy of controls. Annex A, Table A.2 presents the following hierarchy of safeguarding controls:

> 1) elimination or substitution;
> 2) engineering controls (safeguarding technology);
> 3) awareness means;
> 4) training and procedures (administrative controls);
> 5) PPE (Robotics Industries Assn.).

This hierarchy differs from those previously cited in that it adds the element of substituting less-hazardous methods or materials as a means of attaining a tolerable risk level.

SEMI S2-0200

Semiconductor Equipment and Materials International (SEMI) is a trade group for the semiconductor industry. An updated version of SEMI S2-0200, Environmental, Health and Safety Guideline for Semiconductor Manufacturing Equipment, was issued in February 2000. Section 6.8 and 6.8.1 read as follows.

> **6.8** A hazard analysis should be performed to identify and evaluate hazards. The hazard analysis should be initiated early in the design phase and updated as the design matures.
>
> **6.8.1** The hazard analysis should include consideration of:
> - application or process;
> - hazards associated with each task;
> - anticipated failure modes;
> - probability of occurrence and severity of a mishap;
> - level of expertise of exposed personnel and the frequency of exposure;
> - frequency and complexity of operating, servicing and maintenance tasks;
> - safety critical parts (SEMI).

Practitioners engaged in hazard analysis and risk assessment have not agreed on universal definitions for the terms they use. For example, the content of 6.8.1 is described as a hazard analysis. Some may consider it to be an outline for a hazard analysis and a risk assessment.

At 6.9 in the guideline, "the order of precedence for resolving identified hazards" is given: Design to eliminate hazards. Incorporate safety devices. Provide warning devices. Provide hazard warning labels. Develop administrative procedures and training (SEMI). This order of precedence is similar to that set forth in MIL-STD-882D.

MIL-STD-882D

Much of the wording in the preceding hierarchies of control is comparable to that found in military standard system safety requirements. First issued in 1969 as MIL-STD-882, the fourth edition, issued in February 2000 is designated as MIL-STD-882D (U.S. Dept. of Defense). In system safety literature, writers trace the principles embodied in military standard system safety requirements to the work of aviation and space age personnel that commenced after World War II.

The design order of precedence for mitigating hazards as it appears in 882D is an extension of the provisions to satisfy safety requirements shown in the original version of the standard. (Precedence, as used here, means priority in order, rank or importance.) The changes made were derived from 30 years of learning experience. The original requirements were: Design for minimum hazard; safety devices; warning devices; and special procedures.

Section 4.4 in 882D, "Identification of Mishap Risk Mitigation Measures," includes "the system safety design order of precedence for mitigating identified hazards." Section 4.4 follows in its entirety.

4.4 Identification of mishap risk mitigation measures. Identify potential mishap risk mitigation alternatives and the expected effectiveness of each alternative or method. Mishap risk mitigation is an iterative process that culminates when the residual mishap risk has been reduced to a level acceptable to the appropriate authority.

The System Safety Design Order of Precedence for Mitigating Hazards

a) Eliminate hazards through design selection. If unable to eliminate an identified hazard, reduce the associated mishap risk to an acceptable level through design selection.

b) Incorporate safety devices. If unable to eliminate the hazard through design selection, reduce the mishap risk to an acceptable level through using protective safety features or devices.

c) Provide warning devices. If safety devices do not adequately lower the mishap risk of the hazard, include a detection and warning system to alert personnel to the particular hazard.

d) Develop procedures and training. Where it is impractical to eliminate hazards through design selection or to reduce the associated risk to an acceptable level with safety and warning devices, incorporate special procedures and training. Procedures may include the use of personal protective equipment. For hazards assigned catastrophic or critical mishap severity categories, avoid using warning, caution or other written advisory as the only risk reduction method (U.S. Dept. of Defense).

Clearly, the hierarchies of control included in recently issued safety standards and guidelines have been much influenced by the safety design order of precedence as it evolved in the several editions of MIL-STD-882.

ANSI/AIHA Z10

American Industrial Hygiene Assn. (AIHA) is secretariat of ANSI Z10, Occupational Health and Safety Systems. The scope of this draft standard is to "develop a standard of management principles and systems to help organizations design and implement deliberate and documented approaches to continuously improve their occupational health and safety performance" (AIHA). The draft standard contains extensive provisions for risk assessment and the use of a hierarchy of controls. The Z10 Committee is currently evaluating public comment on the draft in accordance with ANSI requirements.

ANSI/PMMI B155.1-2000

The Packaging Machinery Manufacturers Institute (PMMI) is secretariat of ANSI B155.1, Standard for Packaging and Packaging-Related Converting Machinery: Safety Requirements for Construction, Care and Use. Last issued in 2000, the standard is currently under revision. A review of the latest draft indicates that provisions regarding identifying and analyzing hazards, assessing risk, applying a hierarchy of controls and reducing risk to an acceptable level over the lifecycle of the packaging machinery will be expanded (PMMI). The foreword of the draft states, "This version of the standard has been harmonized with European (EN) and international (International Organization for Standardization or ISO) standards by the introduction of hazard identification and risk assessment as the principal method for analyzing hazards to personnel and achieving a level of acceptable risk" (PMMI).

European Influence

Actions in Europe have also provided some impetus to include provisions for hazard analysis, risk assessment and a hierarchy of controls in U.S. standards. Two standards are particularly relevant:

1) ISO 12100-1, Safety of Machinery: Basic Concepts, General Principles for Design—Part 1, which requires that risk assessments be conducted for machinery going into a European workplace [ISO(a)];

2) ISO 14121/EN 1050, Safety of Machinery: Principles of Risk Assessment, which sets forth risk assessment concepts [ISO(b)].

In addition, under several directives from the European Committee for Standardization, American manufacturers that export to Europe are required to place a "CE" mark on their products to indicate that the product complies with all operable directives.

Purpose of a Hierarchy of Control

A hierarchy is any system of actions, things or persons ranked one above the other. For SH&E practitioners, a hierarchy of controls establishes the actions to be considered in an order of effectiveness to resolve unacceptable hazardous situations. Achieving an understanding of the significance and the rationale for this order is an important step in the continuing evolution of the practice of safety.

For many situations, a combination of the risk management methods included in a hierarchy of controls may be applied. However, the expectation is that sequential consideration will be given to each method in a descending order, and that reasonable attempts will be made to eliminate or reduce the hazards and their associated risks by taking the more-effective steps higher in the hierarchy before lower steps are considered. A lower step is not to be chosen until practical applications of the preceding higher levels are exhausted.

The Safety Decision Hierarchy

The following observations are shared as a reflection of the author's experience encompassing the design engineering aspects, operational aspects and post-incident aspects of the practice of safety. SH&E professionals often recommend solutions for hazard/risk situations before they have defined the reality of the problem—that is, before they identify the specifics of the hazards and assess the associated risks. Rarely are systems in place to determine whether the actions that SH&E professionals recommend achieve the intended risk reduction.

Figure 1

Safety Decision Hierarchy

A) Problem Identification & Analysis

1) Identify and analyze hazards.
2) Assess risks.

B) Consider These Actions in Order of Effectiveness

Most Effective

1) Eliminate hazards and risks through system design and redesign.
2) Reduce risks by substituting less-hazardous methods or materials.
3) Incorporate safety devices.
4) Provide warning systems.
5) Apply administrative controls (e.g., work methods, training).
6) Provide PPE.

Least Effective

C) Decide & Take Action

D) Measure for Effectiveness: Reanalyze as Needed

These observations led to exploration of the feasibility of encompassing a hierarchy of controls within established problem-solving techniques. The techniques presented in the several problem-solving texts reviewed have great similarity. Following is a composite of those techniques.

Problem-Solving Methodology

1) Identify the problem.
2) Analyze the problem.
3) Explore alternative solutions.
4) Select and take action.
5) Examine the effects of the action taken.

Can a hierarchy of controls be encompassed within typical problem-solving techniques? Yes, it can and should be. At least one other author has done so:

> Risk engineering techniques provide a thorough, systematic approach to evaluate and reduce occupational hazards. The risk engineering approach includes the following steps.
> 1) Define the facility and environments.
> 2) Identify the hazards.
> 3) Evaluate the risk.
> 4) Develop corrective actions and/or safety design criteria.
> 5) Verify acceptability of risk (Bass 65).

Essentially, this is an adoption of well-publicized problem-solving approaches. In a sense, the Scope and Functions of the Professional Safety Position, first issued by ASSE in 1966 and updated regularly since, also presents a problem-solving methodology:

> The major areas relating to the protection of people, property, and the environment are:
> A) Anticipate, identify and evaluate hazardous conditions and practices.
> B) Develop hazard control designs, methods, procedures and programs.
> C) Implement, administer and advise others on hazard controls and hazard control programs.
> D) Measure, audit and evaluate the effectiveness of hazard controls and hazard control programs (ASSE).

Words/phrases that stand out are anticipate, identify, evaluate, develop hazard control(s), implement hazard controls and measure the effectiveness. That is fundamental problem solving. Figure 1 presents an attempt to encompass a sound hierarchy of controls within sound problem-solving techniques. A description of this process follows.

Problem Identification & Analysis

Problem-solving models typically include a problem identification and analysis phase. In applying the safety decision hierarchy, the goal is to identify and analyze hazards, then assess the associated risks. Hazards and risks cannot be addressed until one determines the severity of harm that can result from a hazardous incident and assesses the probability of such an incident occurring.

Defining Risk Assessment

Unfortunately, a broadly accepted definition of risk assessment has not emerged. *Risk Assessment: Basics and Benchmarks* lists definitions from 19 sources, as well as eight definitions for risk analysis and seven for risk estimation (Main). Clearly, simplicity is needed in defining risk. The following statements are offered to help build that definition.

•Hazards are defined as the potential for harm. The dual nature of hazards must be understood. Hazards include any aspect of technology or activity that produces risk. Hazards include the characteristics of things and the actions or inactions of people.

•Risk is defined as a combination of the probability of a hazard-related incident occurring and the severity of harm or damage that could result.

•Probability is defined as the likelihood of a hazard being realized and initiating an incident or series of incidents that could result in harm or damage—for the selected unit of time, events, population, items or activity being considered.

•Severity is defined as the extent of harm or damage that could result from a hazard-related incident.

•The entirety of purpose of those accountable for safety, whatever their titles, is to manage their endeavors with respect to hazards so that their associated risks are acceptable.

Risk assessment commences with hazard identification and analysis, through which the probable severity of harm is established (assuming that a hazard's potential is realized and a hazard-related incident occurs); it concludes with an estimate of the probability of the hazard-related incident occurring. An appropriate statement indicating risk level must include both the probability of a hazard-related incident occurring (related to some statistical base) and the severity of harm or damage that could result. If a risk assessment establishes that risks are not acceptable, appropriate abatement actions would taken.

Hazard Analysis & Risk Assessment Guide

Following is a general guide on how to perform a hazard analysis and a risk assessment. Specific methods to be applied for risk assessment are not prescribed in the standards and guidelines previously cited. The intent is that the technique best-suited to the given hazard/risk situation be applied. Many such methodologies are available. For example, the *System Safety Handbook* describes 101 analytical methods (Stephans and Talso). Commonly used techniques include preliminary hazard analysis; safety reviews; operations analysis; what-if analysis; checklist analysis; what-if checklist analysis; hazard and operability analysis (HAZOP); failure modes and effects analysis; fault-tree analysis; and management oversight and risk tree [Manuele(a)].

Whatever the simplicity or complexity of the hazard/risk situation, and whatever the risk assessment methodology used, the following thought-and-action process is applicable.

1) **Establish analysis parameters.** Select a manageable task, system, process or product to be analyzed, and establish its boundaries and operating phase (e.g., standard operation, maintenance, startup). Determine the scope of the analysis in terms of what can be harmed or damaged: People (the public, employees), property, equipment, productivity and the environment.

2) **Identify the hazards.** The frame of thinking adopted should get to the bases of causal factors, which are hazards. These questions should be asked: What characteristics of things or the actions or inactions of people present a potential for harm? What aspects of the activity or technology produce risk?

Depending on the complexity of the situation, some or all of the following may apply.

- Use intuitive engineering and operational sense. This is paramount throughout.
- Examine system specifications and expectations.
- Review relevant codes, regulations and consensus standards.
- Interview current or intended system users or operators.
- Consult checklists.
- Review studies from similar systems.
- Consider the potential for unwanted energy releases and exposure to hazardous substances.
- Review historical data such as industry experience, incident investigation reports, OSHA and National Safety Council data, and manufacturers' literature.
- Brainstorm.

3) **Consider the failure modes.** Define possible failure modes that would result in the realization of the potentials of the hazards. Consider how an undesirable event could occur and what controls are in place to mitigate its occurrence.

4) **Determine exposure frequency and duration.** For each harm or damage category selected in Step 1 for the scope of the analysis, estimate the frequency and duration of exposure to the hazard (i.e., the frequency and duration of vulnerability or endangerment). For example, for workers, consider how often the task is performed, the duration of exposure and the number of people affected.

5) **Assess the severity of consequences.** What is the magnitude of harm or damage that could result? Learned speculations must be made regarding the consequences of an occurrence: The number of resulting injuries and illnesses or fatalities; the value of property or equipment damaged; the duration of lost productivity; or the extent of environmental damage. Historical data can establish a baseline. On a subjective basis, the goal is to determine the worst-credible consequences should an incident occur, not the worst-conceivable consequences. When the severity of consequences is determined, the hazard analysis is complete.

6) **Determine occurrence probability.** Consider the likelihood that a hazardous event will occur. This process is also subjective. For more-complex hazardous scenarios, it is best to brainstorm with people knowledgeable of the issues involved. Probability is to be related to an interval base of some sort, such as a unit of time or activity, events, units produced, or the life cycle of a facility, equipment, process or product.

7) **Define the risk.** Conclude with a statement that addresses both the probability of an incident occurring and the expected severity of harm or damage. Categorize each risk in accord with agreed-upon terms, such as high, serious, moderate or low.

8) **Rank risks in priority order.** Risks should be ranked in order to establish priorities. Since the hazard analysis and risk assessment exercise is subjective, the risk-ranking system will also be subjective.

9) **Develop remediation proposals.** When required by the results of the risk assessment, alternate proposals for design and operational changes that are needed to achieve an acceptable risk level would be recommended.

10) **Take action.** Action should be taken as necessary, as should follow-up activities to determine whether the action was effective.

The safety decision hierarchy helps one identify and analyze hazards, then assess the associated risks. Neither can be addressed until one determines the severity of harm that can result from an incident and assesses the probability of such an incident occurring.

Risk Assessment Matrixes

The author has collected 15 risk assessment matrixes—some simple, some complex. Each matrix presents categories of incident occurrence probability and the severity of harm or damage that could result. A risk assessment matrix is a method to display the combinations of probability and severity and to categorize those combinations. Such a matrix also helps the SH&E professional communicate with and influence decision makers [Manuele(a)].

Table 1

Risk Assessment Matrix

OCCURRENCE PROBABILITY	SEVERITY OF CONSEQUENCES Catastrophic	Critical	Medium	Minimal
Frequent	High	High	Serious	Moderate
Likely	High	High	Serious	Moderate
Occasional	Serious	Serious	Moderate	Low
Remote	Moderate	Moderate	Moderate	Low
Improbable	Low	Low	Low	Low

Table 2

Management Decision Levels

Risk Category	Remedial Action or Acceptance
High	Operation not permissible.
Serious	Remedial action to have high priority.
Moderate	Remedial action to be taken in appropriate time.
Low	Risk is acceptable; remedial action is discretionary.

It is best to adopt or develop a risk assessment matrix that is suitable to an entity's particular needs. In this process, one must ensure that the meanings of the terms contained in the matrix are understood by those making risk assessments and by decision makers. While various matrixes may contain the same terms—such as the probability of an incident occurring being frequent or likely, and the severity of consequences being high or serious—they may have different descriptions. For illustration, Table 1 presents a risk assessment matrix while Table 2 illustrates possible management decision levels.

The Logic of Taking Action in an Order of Effectiveness

In the safety decision hierarchy, alternative risk reduction and elimination actions are listed in descending order of effectiveness. Sound safety management requires that one establish the rationale for the order in which the list is presented.

Actions described in the first, second and third levels are more effective because they 1) are preventive actions that reduce risk by design and substitution measures; 2) rely least on personnel performance; and 3) are less defeatable. Actions described in the fourth, fifth and sixth levels rely greatly on the performance of people.

Action Level 1

If the hazards are eliminated in the design and redesign processes, risks that derive from those hazards are also eliminated. The intent is to design to acceptable risk and to minimize the human action necessary in the work process. Examples include designing to eliminate hazards related to falls, ergonomics, confined spaces, noise and chemicals. If no hazards are present, there is no potential for harm, and, thereby, no risk.

Action Level 2

By substituting less-hazardous methods or materials, risks can be substantively reduced. Examples include using automated materials handling equipment rather than manual materials handling; providing an automatic feed system to reduce machine hazards; using a less-hazardous cleaning material; and replacing an old steam heating system and its boiler explosion hazards with a hot air system. This reduces the need to rely on the actions of people, although perhaps not to the same extent as designing out the hazard.

Note that this hierarchy of controls separates eliminating hazards and risks in the design process from substituting less-hazardous methods/materials. Based on the author's experience, substitution of a less-hazardous method/material may or may not result in equivalent risk reduction in relation to what might be the case if hazards and risks are reduced through design engineering.

Consider this example: The mixing process for chemicals often requires considerable manual materials handling. A reaction occurs and an employee sustains serious chemical burns.

Identical operations are performed at two of this company's locations. At one, management decides to re-engineer the operation so it is completely enclosed, automatically fed and operated by computer from a control panel. At the other location, no funds are available for re-engineering, so site management arranges for the supplier to premix the chemicals before shipment and installs some mechanical feed equipment for the chemicals. The risk reduction achieved as a result would not be equivalent to that attained by re-engineering the operation.

In another example, if a 110-volt power source replaces an 880-volt power source, the injurious power level has been reduced, but 110 volts with the necessary amperage can still be fatal.

Action Level 3

When safety devices are incorporated into the system or product in the form of engineering controls, risk can be reduced, as can reliance on the worker or product user's actions. Safety devices include machine guarding, interlock systems, presence-sensing devices, safety nets, fall prevention systems, and all devices and systems that separate hazardous energy from personnel.

Action Level 4

Warning systems, although vital in many situations, are reactionary. They alert people only after a hazard's potential is in the process of being realized (e.g., a smoke alarm). Warning system effectiveness and the effectiveness of instructions, signs and warning labels rely considerably on administrative controls, training, the quality of maintenance and people's reactions.

A note about the term "warning systems." In one published hierarchy of control, the designation for this purpose is merely "warning signs"; in another, it is simply "warnings." The entirety of the needs of a warning system must be considered, for which warning signs alone may be inadequate. For example, NFPA Life Safety Code 101 may require, among other things: smoke and products-of-combustion detectors; automatic and manual audible and visible alarms; lighted exit signs; designated, alternate, properly lit exit paths; adequate spacing for personnel at the end of the exit path; proper hardware for doors; and emergency power systems.

Action Level 5

Administrative controls include appropriate work methods and procedures, personnel selection, training, supervision, motivation, work scheduling, job rotation, scheduled rest periods, maintenance, management of change, investigations, inspections and behavior modification. These controls rely on the appropriateness of the particular method in relation to needs, capabilities of those responsible for their delivery and application, quality of supervision and performance of workers. It is difficult to achieve a superior level of effectiveness in all these areas.

Action Level 6

Proper use of PPE—such as safety glasses, faceshields, safety shoes, gloves and hearing protection—relies on an extensive series of supervisory and personal actions, such as the identification of the equipment needed, and its selection, fitting, training, inspection and maintenance. Although use of PPE is common and it is necessary in many occupational situations, it is the least-effective method to address hazards and risks; it is also a method that can be easily defeated.

Deciding & Taking Action

The next step is to decide on and take action. Once this decision is made, some fundamental management practices are necessary, such as assigning responsibility, scheduling, providing resources (staffing and money) and setting target dates for completion—all of which must be documented.

Measuring for Effectiveness & Reanalyzing as Necessary

Ensuring that actions taken accomplish their intended goal is an integral step in an effective problem-solving technique. For safety management purposes, measuring for effectiveness requires verifying whether actions taken have truly reduced the risk to the level expected. Follow-up activity would determine whether the solutions were effective.

- The problem was resolved, only partially resolved or not affected.
- All hazards were or were not addressed.
- Actions taken did or did not create new hazards.

No matter what actions are taken, if a work activity continues, it will always produce residual risk (risk that remains after preventive measures have been taken). It is not possible to attain zero risk. If the residual risk is not acceptable, the thought process involved with the safety decision hierarchy must be reapplied, beginning with hazard identification and analysis process.

Conclusion

Requirements for risk assessment and hierarchies of control are now common components of safety standards and guidelines. As these provisions become more prevalent, SH&E professionals must takes steps to understand them in order to effectively apply these techniques. ■

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