Risk Assessment Is Coming: Are You Ready?

Understanding the risk assessment process and its benefits

By Bruce W. Main

RISK ASSESSMENT IS POISED to enter the mainstream of business and industry through the standards process. What started as an informative process of technical reports and guidelines is quickly becoming specific requirements in industry standards. These requirements place risk assessment responsibilities on both equipment suppliers (manufacturers) and users (employers). Did you know? Are you ready?

Risk assessments will soon be required on all machines covered by the ANSI B11 (machine tool) standards. Safety practitioners need to learn about the requirements for—and benefits of—risk assessment. Equipment buyers will likely begin to require risk assessment with their purchases, and integrators will ask for risk assessment from suppliers. In turn, users will eventually require risk assessments for equipment. As a result, risk assessment will eventually become like quality—understood, integrated and an expected part of doing business. Now is the time to prepare for this evolution and learn what is expected from suppliers and users.

This article reviews the recent progression of risk assessment, explains supplier and user responsibilities in the machine tool industry, presents other-industry and cross-industry evidence of risk assessment advances, and discusses the implications of these changes.

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Background

The Assn. for Manufacturing Technology (AMT) is the accredited standards-developing organization for the U.S. machine tool industry (ANSI B11 Machine Tool Safety Standards). The B11 community writes safety standards for power-driven machine tools (not hand-portable); these standards are applicable to the design, construction, installation, maintenance and use of power-driven machines used to shape or form metal or other materials by cutting, impact, pressure, electrical techniques or a combination of these processes. The purpose of the B11 series is "to devise and propose ways to minimize risks associated with existing and potential hazards. This can be accomplished by an appropriate machine design, by restricting personnel access to hazardous areas or by devising work procedures to minimize personnel exposure to hazardous situations." Table 1 lists the current standards in the series.

In 1995, members of the B11 community were discussing the concepts of risk assessment, particularly in light of the then-new European standard EN 1050 (now ISO 14121). A subcommittee was formed to develop a technical report to provide guidance for the application of risk assessment principles to machine tools during design, installation and use phases. One of the group's explicit goals was to develop a single risk assessment process that would be appropriate for the U.S. machine tool industry and could be integrated into all existing B11 standards; an initial draft document was developed in April 1996.

Progression

Over the course of several years and through much debate, the subcommittee worked to develop a risk assessment process and a document that described it. The result of these efforts was released in late 2000 as "Risk Assessment and Risk Reduction: A Guide to Estimate, Evaluate and Reduce Risks Associated with Machine Tools." Commonly known as "TR3" (as it is the third technical report published by ANSI B11), this document was released as an informative technical report. As

such, it is an informative resource equivalent to other technical information; no industry or government requirement mandates that the content of a technical report be followed.

According to TR3:

> This technical report provides guidance for machine suppliers and users to analyze and reduce risks associated with hazards generated by machines and associated equipment where it is possible for persons to come in contact with or otherwise be affected by these hazards. Its use is intended for all new or modified machines and equipment designs and processes, but the user may also use it to assist with risk assessment and risk reduction for existing tasks and hazards—appreciating that many engineered safeguards are often not feasible to retrofit existing equipment.

During the formative years of TR3, subcommittee members experimented with different aspects of risk assessment in their respective companies and consulting work. As experience with the process grew, these members recognized its benefits, and discussions moved from whether risk assessment should be performed to implementation issues of how and when. As these benefits become apparent, risk assessment requirements are working their way into industry standards. Once TR3 was complete, the B11 community moved quickly to begin integrating risk assessment into the B11 standards.

The Goal

The goal of conducting a risk assessment is to reduce risks to an acceptable (or tolerable) level; the goal is *not* to work to zero risk. The introduction to TR3 states, "This technical report recognizes that zero risk does not exist and cannot be attained. However, a good-faith approach to risk assessment and risk reduction as described in this guide should achieve a tolerable risk level." [See Manuele and Main for further discussion of tolerable (or acceptable) risk.]

B11 Standards Organization

The B11 standards use the following general organizational structure (with slight differences in some cases):

Foreword
Introduction
1) Scope
2) Normative References
3) Definitions
4) Responsibility
5) Hazard Control
6) Design and Construction
7) Layout, Installation, Testing and Start-Up
8) Safeguarding
9) Set-Up, Operation and Maintenance
Annexes

The foreword, introduction and annexes contain advisory information but are not considered part of the requirements of the B11 standards.

As with all ANSI standards, the B11 standards face a 10-year renewal/approval cycle. Each standard must be renewed, reapproved or revised in this cycle or it is automatically withdrawn. Many of the B11 standards are nearing the end of their cycles and the writing committees are busy revising the standards (Table 1). Over the next four years, each B11 standard will be revised and updated to include the risk assessment process; the first standards to complete this process will be released this year.

Suppliers, Users & Personnel

Within the standards, three specific entities have responsibilities: suppliers, users and personnel. The following definitions are excerpted from TR3 and the most recent draft of B11.20, Safety Requirements for Manufacturing Systems/Cells:

- *Supplier:* An entity that provides or makes avail-

Table 1

B11 Machine Tools Standards

Reference	Title*	Publication Date (Rev.)
B11.1	Mechanical Power Presses	1988 (R94)
B11.2	Hydraulic Power Presses	1995 (R00)
B11.3	Power Press Brakes	1982 (R94)
B11.4	Shears	1993
B11.5	Iron Workers	1988 (R94)
B11.6	Manual Turning Machines with/ without automatic control	1984 (R94)
B11.7	Cold Headers & Cold Formers	1995 (R00)
B11.8	Manual Milling, Drilling & Boring Machines with/without automatic control	1983 (R94)
B11.9	Grinding Machines (GWI-SDO)	1975 (R97)
B11.10	Metal Sawing Machines	1990 (R98)
B11.11	Gear [Spline] Cutting Machines	1985 (R94)
B11.12	Roll Forming & Roll Bending Machines	1996
B11.13	Automatic Screw/Bar & Chucking Machines	1992 (R98)
B11.14	Coil Slitting Machines	1996
B11.15	Pipe, Tube & Shape Bending Machines	1984 (R94)
B11.16	Metal Powder Compacting Presses	1988
B11.17	Horizontal Hydraulic Extrusion Presses	1996
B11.18	Coil Processing Systems	1997
B11.19	Safeguarding Methods	1990 (R97)
B11.20	Manufacturing Systems/Cells	1991 (R97)
B11.21	Machines Using Lasers	1997
B11.22	Numerically Controlled Turning Machines	NEW
B11.23	Machining Centers	NEW
B11.24	Transfer Machines	NEW

**See www.mfgtech.org for more information on the B11 standards.*

Table 2

B11.01 Power Press Standard: Clause 4, Responsibility

4.1 Supplier

For purposes of this standard, the supplier can be the manufacturer, integrator, modifier, rebuilder or installer of the mechanical power press.

Within the scope of the work activity, the supplier shall be responsible to ensure that the design, construction, modification, installation and safeguarding are in accordance with clauses 6, 7 and 8.

4.1.1 Task & hazard identification

The supplier shall be responsible for identifying sources of hazards within the scope of their work activity in accordance with 5.1.

E4.1.1 See also Annex B for additional information.

4.1.2 Risk assessment/risk reduction

The supplier shall be responsible for assessing and reducing the risks identified in 4.1.1, in accordance with 5.1.

4.1.3 Documentation (information for use)

The supplier shall be responsible for providing documentation to the user that establishes guidelines for the installation, operation and maintenance of the mechanical power press or press production system.

E4.1.3 The documentation should include, but not be limited to, the following, where applicable:

a) performance specifications;
b) electrical or pneumatic schematics and diagrams;
c) physical environment for which the machine or production system is designed;
d) function and location of the operator controls, indicators and displays;
e) schedules for periodic maintenance, lubrication and inspection;
f) application of protective measures;
g) auxiliary equipment.

4.2 User

When the user designs, constructs, installs, modifies or reconstructs the power press or press production system, the user is considered to be the supplier. See 4.1.

4.2.1 Installation

The user shall have the responsibility for installation of a press production system in accordance with clause 7.

4.2.2 Hazard identification

The user shall have the responsibility to identify point of operation and other hazards involved with all tasks to be implemented during the operation of a press production system, in accordance with 5.1.

E4.2.2 See also clause 8.

4.2.3 Hazard control

The user shall have the responsibility to provide, maintain and ensure the correct use of safeguarding for all hazards identified.

E4.2.3 For safeguarding of auxiliary equipment, see B11.19.

4.2.4 Set-up, operation & maintenance

The user shall have the responsibility for the set-up, operation and maintenance of a press production system in accordance with clause 9.

4.3 User personnel

User personnel shall be responsible for ensuring their own personal safety and well-being.

User personnel shall be responsible for complying with operating procedures and safe working procedures provided by the user. (See clause 9).

E4.3 Section 5(b) of the Occupational Safety and Health Act of 1970—Public Law 91-596 states:

"Each employee shall comply with the occupational safety and health standards and all rules, regulations and orders issued pursuant to this Act which are applicable to his/her own actions and conduct."

able for use all or part of a [machine] or [system]. Note: Under certain circumstances (i.e., acting as a builder, modifier, integrator), the user may act as a supplier.

•*User:* An entity that utilizes the [machine], [system] or related equipment. Note: Under certain circumstances (i.e., acting as a builder, modifier, integrator), the user may act as a supplier.

•*Personnel:* An individual or individuals who are employed by the user and trained for a specific task(s).

Typically, the supplier is the machine tool manufacturer or integrator, the user is the company purchasing the machine (the employer) and the personnel are the workers at the user's facility.

Responsibilities

TR3 includes the following passage on risk assessment responsibilities:

> **4.3.1** Both the supplier of the machine and the user of the machine have risk assessment and risk reduction responsibilities. When the supplier is not available to participate in the risk assessment for the machine, the user assumes this responsibility.

Clause 4 of the B11 standards explicitly identifies the responsibilities of the machine supplier, user and personnel. Table 2 presents this clause from the forthcoming B11.01 Power Press Standard. Note that clause 5.1 is explicitly referenced for the supplier under 4.1.1 and for the user under 4.2.2. Clause 5.1 refers to task and hazard identification, one of the first steps in conducting a risk assessment.

Risk Assessment

Clause 5 describes the general risk assessment process and requirements for conducting a risk assessment. Requirements for task-based risk assessment are made explicitly within the standards and via references to TR3. Table 3 presents clause 5 from B11.01. Risk assessment is necessary for compliance with clauses 4 and 5. Furthermore, these clauses demonstrate the tight integration of TR3 and risk assessment into the standard.

Risk Reduction

The primary reason to assess risk is to reduce it, thus risk reduction is part of the TR3 risk assessment process. TR3 includes the hierarchy of controls familiar to safety practitioners:

1) Eliminate or control hazard(s) by design.

2) Control exposure to hazards by use of guards or safeguarding devices.

3) Provide other safety measures (e.g., awareness signals and barriers).

4) Use administrative controls or other protective measures (e.g., preventive maintenance, personal protective equipment, warning signs).

The B11 standards include the following text on risk reduction:

> Risk reduction is complete when the protective measures, consistent with the standards, are applied and tolerable risk has been achieved for the identified task/hazard combinations and the machine or machine production system as a whole.

Documentation

One element of risk assessment that differs from many current practices is the documentation requirement. According to clause 9 of TR3, the risk assessment must be documented as follows:

9.1 Supplier Documentation

Supplier documentation of the risk assessment and the risk reduction process should demonstrate the procedure that has been followed and the results that have been achieved. The supplier should provide documentation of the protective measures taken and recommendations for additional protective measures to be implemented by the user, system integrator or other entity involved in machine utilization.

9.2 User Documentation

User documentation of the risk assessment and the risk reduction process should demonstrate the procedure that has been followed and the results that have been achieved. The user documentation should include the protective measures taken and the resulting residual risks.

9.3 Cooperation Between Supplier & User

Cooperation between the supplier and user is encouraged for the risk assessment and risk reduction process, and documentation of the process.

Supplier and user risk assessment and risk reduction documentation includes:

a) machine for which the assessment has been made (e.g., specifications, limits, intended use);

b) any relevant assumptions made (e.g., loads, strengths, safety [design] factors);

c) hazardous situations (task/hazard pairs) that have been identified;

d) information on which risk assessment was based (see 4.2);

- data used and sources (e.g., accident histories, experiences gained from risk reduction applied to similar machines);
- uncertainty associated with the data used and its impact on the risk assessment;

e) objectives to be achieved by protective measures;

f) protective measures implemented to eliminate identified hazards or to reduce risk (e.g., from standards or other specifications);

g) residual risks associated with the machine.

The requirement to document the risk assessment is consistent across many industries that address risk assessment (ANSI/RIA R15.06-1999; ANSI PMMI B155.1-2000; SEMI S10 1296; *Risk Management Guide*). This stems from the quality movement.

So, Is This Approach All That Different?

Is risk assessment so very different than what is currently being done? Yes and no.

No, one should not expect to dramatically redesign systems in response to risk assessment results. Risk assessment has been conducted in various forms for many years, if only informally. In most cases, risk assessment will build on past successes and will not require a complete redesign. In the few cases where major redesign is necessary, it will occur because hazards identified will pose unacceptably high risks. This is a business decision similar to other decisions currently made. In most cases, the assessment will only disclose situations that may benefit from additional risk-reduction efforts. Immediate risk reduction for existing designs often includes additional administrative controls such as specific new instructions or training. Subsequent risk reduction often includes implementing engineering improvements as practical. If the risk assessment is conducted early in the design process, then engineering controls can be used to reduce risk.

Yes, risk assessments are different because of the level of detail involved and documentation requirements. Through the task-based approach, risk assessments require a thorough analysis of what users do with a machine tool. This level of detail may be different than analyses conducted previously.

Some safety analyses are conducted via design reviews or general undocumented evaluations. Such efforts often do not require the level of follow-through that occurs due to a documented analysis. Documentation requirements present a substantial change in how the B11 community addresses safety. Although TR3 and other guidelines require that a risk assessment be documented, the B11 standards do not require that the supplier provide a documented risk assessment to the user. (See clause 4.1.3 of Table 2.) The risk assessment is not part of the information for use nor is it required to be provided

Useful Definitions

These definitions are from B11 TR3 (2000):

3.3 *Harm:* Physical injury or damage to health of people. Note: This may be a result of direct interaction with the [machine] or indirectly as a result of damage to property or to the environment.

3.4 *Hazard:* A potential source of harm.

3.13 *Protective measures:* Design, safeguards and complementary protective devices, administrative controls ; warnings, work procedures, training or personal protective equipment used to eliminate hazards or reduce risks.

3.15 *Residual risk:* Risk remaining after protective measures have been taken.

3.16 *Risk:* A combination of the probability of occurrence of harm and the severity of that harm.

3.17 *Risk assessment:* The process by which the intended use of the machine, tasks and hazards, and the level of risk are determined.

3.22 *Tolerable risk:* Risk that is accepted for a given task and hazard combination [hazardous situation].

Table 3

B11.01 Power Press Standard: Clause 5, Task & Hazard Identification, Risk Assessment & Risk Reduction

5.1 Task & hazard identification

Reasonably foreseeable tasks and associated hazards shall be identified throughout the lifecycle (design, installation, set-up, operation and maintenance) of the press.

E5.1 Task identification should take into account, but not be limited to, the following task categories:

a) packing and transportation;
b) unloading/unpacking;
c) systems installation;
d) start-up/commissioning;
e) set-up and tryout (debug);
f) operation (all modes);
g) tool change;
h) planned maintenance;
i) unplanned maintenance;
j) major repair;
k) recovery from control failure;
l) recovery from jam;
m) troubleshooting;
n) housekeeping;
o) decommissioning;
p) disposal.

For each of the task categories there may be many tasks. Tasks are specific activities that relate to the task category. Each task category may have numerous tasks associated with it. Examples specific to presses include but are not limited to:

a) workpiece feeding;
b) changing a die;
c) changing a material coil (where applicable);
d) replacing a drive belt;
e) replacing a filter;
f) troubleshooting a press repeatability problem;
g) unsticking scrap or parts.

For each of the above tasks, there may be numerous hazards. Examples of hazards and hazardous situations addressed within this standard (design/construction, installation, setup, operation and maintenance) are contained in Annex B.

In addition, reasonably foreseeable hazards not directly related to tasks shall be identified.

Following are some examples of reasonably foreseeable hazards not related to tasks:

a) failure of a high pressure hydraulic line;
b) bearing failure or bearing seizure;
c) failure of the structural components of the machine.

Tasks and associated hazards shall be identified and reassessed when necessary or whenever the machine is modified or its typical use is changed (see 5.2).

Each time a mechanical power press is modified or its use is changed, the tasks/hazards associated with the modification or change should be identified and reassessed.

For a more detailed discussion on task/hazard combination identification, refer to ANSI B11.TR3.

5.2 Risk assessment/risk reduction

Risks associated with the task/hazard combinations identified in 5.1, including reasonably foreseeable hazards not directly related to tasks, shall be assessed and reduced to a tolerable level by incorporating one or more of the following protective measures, in hierarchical order:

a) eliminate or control hazard(s) by design;
b) control exposure to hazards by the use of guards or safeguarding devices;
c) provide other safeguarding (e.g., awareness barriers, awareness signals and safeguarding methods);
d) implement administrative controls or other protective measures (including safe work procedures, preventive maintenance, training, retraining, personal protective equipment and warning signs).

E5.2 Where possible and when necessary, the user, in conjunction with the supplier, should ensure that the task/hazard combinations and reasonably foreseeable hazards not directly related to tasks (and their associated protective measures) identified in this standard are appropriate for mechanical power presses or press production systems. For further information on risk assessment, see ANSI B11.TR3.

When performing risk reduction for task/hazard combinations identified in 5.1, including reasonably foreseeable hazards not directly related to tasks, the requirements of clauses 6, 7, 8, 9 and 10 shall be implemented.

For performing risk reduction on task/hazard combinations and reasonably foreseeable hazards not directly related to tasks not resolved by applying clauses 6, 7, 8, 9 and 10, see ANSI B11.TR3.

Tolerable risk shall be determined by evaluating the application of the protective measures against the following factors:

a) risk-reduction benefit;

Risk-reduction benefit is determined by estimating the potential reduction in severity of harm or probability of occurrence of harm. The type of protective measure is determined by the nature of the task and associated hazard(s) for the machine under consideration. Protective measures should be selected to provide the desired degree of risk reduction.

b) technological feasibility;
c) economic feasibility;
d) ergonomic impact;
e) productivity;
f) durability and maintainability;
g) usability.

Risk reduction is complete when the protective measures, consistent with this standard, are applied and tolerable risk has been achieved for the identified task/hazard combinations and the mechanical power press or press production system as a whole.

by the supplier. In many cases, suppliers consider assessment results to be proprietary information. They may be willing to let purchasers view the information but may not be willing to provide a copy outright. However, as more users begin conducting risk assessments, users will likely begin to request supplier risk assessments.

What Exactly Is Required?

Requirements for a specific machine tool depend on the machine and are contained in the applicable B11 standard and TR3 (copies of which are available from AMT—www.mfgtech.org). Those who do not make or use machine tools are not necessarily free from requirements of risk assessment. In recent

years, many industry committees have written technical reports or guidelines on how to perform risk assessments; these include:

- robotics industries (www.robotics.org);
- semiconductor and flat panel industries (www.semi.org);
- packaging machine industries (www.pmmi.org);
- aviation ground operations (www.nsc.org) (*Risk Management Guide*);
- U.S. military (MIL-STD-882D) (DoD).

Several other industries are currently writing risk assessment clauses into their standards as well.

Cross-Industry Standards

In addition to individual industry requirements, risk assessment is also appearing in cross-industry standards. For example, the current draft of ANSI Z244, Control of Hazardous Energy: Lockout/Tagout and Alternative Methods, integrates risk assessment extensively as the following excerpts illustrate:

> A risk assessment shall be performed during the engineering design stage of development to determine the need for and design sufficiency of appropriate energy isolating devices and systems (from clause 5.1).
>
> However, before adopting alternative methods of control, the user shall conduct a risk assessment that demonstrates the adequacy of the evaluation and the effectiveness of the protective measures (from clause 6.1).
>
> Selection of an alternative control method by the user shall be based on a risk assessment of the machine, equipment or process as specified in 6.3.1. (from clause 6.3) (NSC).

In addition, other text indicates that decisions on using warnings, personal protective equipment or other risk-reduction methods are to be based on risk assessment as are situations that do not permit traditional lockout/tagout methods. Although this language is subject to change or may be deleted by the drafting committee before it releases the final document, these excerpts illustrate how risk assessment is integrated into the standard.

Why All This Trouble?

One might reasonably ask, "Why go to all this trouble when a given product line has a long and successful history?" This is a fair question and the answer does not include any magic secrets. The fundamental reason that risk assessment is advancing so quickly is because it works. It helps the user identify more hazards; prompts those involved to address resulting risks earlier in the design process (before an incident occurs); and provides a better understanding of what people do. The end result is better, safer, more-productive and more-competitive designs. Risk assessment is not intended to ignore or displace current designs, risk-reduction methods or past successes; it is intended as a means to improve on current successes.

Carrot or Stick?

Depending on one's perspective, risk assessment comes with a perceived potential benefit or threat. The benefit is that risk assessment works; companies that are embracing it are realizing significant productivity gains and cost efficiencies that lead to competitive advantage. New software tools and resources greatly increase the ability to conduct such analysis to a greater level of detail and understanding than what was practical even a few years ago. (Design Safety Engineering; Packaging Machine Manufacturers Institute; RIA; SEMI).

The perceived threat is that a firm will not comply with an industry standard that could create legal liabilities or lead to OSHA citations (Ross and Main).

Conclusion

Risk assessments, proven effective in prototype efforts, are now entering mainstream industry through the standards process. Risk assessment will eventually become like quality—understood, integrated and an expected part of doing business. Safety practitioners need to learn about risk assessment requirements and the risk assessment process so they can share in the benefits that others are obtaining. ■

The fundamental reason that risk assessment is advancing so quickly is because it works.

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