Three Case Studies for the Risk Management Framework for Hazardous Materials Transportation

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TABLE OF CONTENTS

| 1. | BACKGROUND | I |
|----|---------------------------------------------------------------------------------------------------------------|--------|
| | 1.1 THE CASE STUDIES | 1 |
| | 1.2 THE RISK MANAGEMENT FRAMEWORK | |
| 2. | CASE STUDY #1: THE NON-ACCIDENTAL RELEASE PROGRAM | |
| | ADMINISTERED BY THE ASSOCIATION OF AMERICAN RAILROADS | 4 |
| | 2.1 Dispersion and Company NAD December 1 | |
| | 2.1 RATIONALE FOR SELECTING NAR PROGRAM | |
| | 2.2 DESCRIPTION OF NAR PROGRAM | |
| | 2.3.1 Comparison of the NAR Program with the Proposed Framework's Philosophy | |
| | 2.3.1 Comparison of the NAR Program with the Proposed Framework's Principles | 5 6 |
| | 2.3.3 Comparison of the NAR Program with the Proposed Framework's Generic, Stepwise Risk | 0 |
| | Management Approach | 8 |
| | 2.3.4 Observations | |
| | 2.4 CONCLUSIONS | 11 |
| | 2.4.1 What are Differences and Similarities Between the Proposed Risk Management Framework and t NAR Program? | |
| | 2.4.2 Did the Proposed Risk Management Framework Prove to be Flexible and Adaptable? | |
| | 2.4.3 Did the Proposed Risk Management Framework Help to Structure Improvements to the NAR | |
| | Program? | 12 |
| 2 | CASE STUDY # 2 - RSPA'S EXEMPTIONS PROGRAM AND THE REGULATED | |
| 3. | | |
| | MEDICAL WASTE EXEMPTION | . 14 |
| | 3.1 RATIONALE FOR SELECTING RSPA'S EXEMPTIONS PROGRAM | 14 |
| | 3.2 DESCRIPTION OF RSPA'S EXEMPTIONS PROGRAM | |
| | 3.3 THE REGULATED MEDICAL WASTE BULK PACKAGING AND TRANSPORT EXEMPTION | 15 |
| | 3.4 THE EXEMPTIONS PROGRAM AND THE RISK MANAGEMENT FRAMEWORK | |
| | 3.4.1 Comparison of the Exemptions Program to the Proposed Risk Management Framework's Philoso | |
| | 3.4.2 Comparison of the Exemptions Program to the Proposed Risk Management Framework's Princip | oles |
| | | 18 |
| | 3.4.3 Comparison of the Exemptions Program to the Proposed Framework's Generic, Stepwise Risk | |
| | Management Approach | |
| | 3.4.4 Observations | |
| | 3.5 CONCLUSIONS | 24 |
| | 3.5.1 What Are the Major Differences and Similarities Between the Proposed Risk Management | 2.1 |
| | Framework and RSPA's Exemptions Program? | |
| | 5.5.2 Dia ine Proposea Kisk Managemeni Framework Prove to be Flexible, Adaptable, and Osejui? | 24 |
| 4. | CASE STUDY #3: COMPILATION OF RISK MANAGEMENT APPROACHES US | ED |
| | BY SELECTED MEMBERS OF TRUCKING INDUSTRY | . 25 |
| | | |
| | 4.1 RATIONALE FOR SELECTING AND METHODOLOGY FOR STUDYING RISK MANAGEMENT APPROACHES | |
| | 4.2 COMPILATION OF RISK MANAGEMENT APPROACHES | |
| | 4.2.1 Understanding and Evaluating the Hazards and Risks 4.2.2 Addressing the Hazards | |
| | 4.2.3 Continuous Improvement and Evaluation | |
| | 4.2.4 Management Commitment | |
| | 4.3 COMPARISON OF RISK MANAGEMENT APPROACHES WITH PROPOSED RISK MANAGEMENT FRAMEWORK | |
| | 4.4 CONCLUSIONS. | |
| | 4.4.1 What Are the Major Differences and Similarities Between the Proposed Risk Management | / |
| | Framework and the Risk Management Approaches Used by Selected Trucking Companies? | 29 |
| | 4.4.2 Did the Proposed Risk Management Framework Prove to be Flexible, Adaptable, and Useful? | |
| | · | |

EXHIBITS

| Exhibit 1. | A Generic, Stepwise Approach to Risk Management for Hazardous Materials Transportation |
|------------|--------------------------------------------------------------------------------------------------|
| Exhibit 2. | Types of NAR Program Activities |
| Exhibit 3. | Comparison of Framework Principles and the NAR Program Activities/Elements 7 |
| Exhibit 4. | A Proposed Generic, Stepwise Approach to Risk Management for Hazardous Materials Transportation |
| Exhibit 5. | The NAR Program Flowchart and Equivalent Proposed Generic, Approach Steps $\dots 10$ |
| Exhibit 6. | Comparison of Proposed Framework Principles and RSPA or Applicant Activities . 19 |
| Exhibit 7. | The Exemptions Program Flowchart and Equivalent Proposed Stepwise, Generic Approach Steps |

1. Background

The Department of Transportation (DOT) administers a comprehensive safety program in hazardous materials transportation to protect the Nation from the risk to life, health, property, and the environment. The existing hazardous materials transportation safety program has performed well over the years. In an effort to further reduce the number and impact of serious accidents involving the transport of hazardous materials, the Department of Transportation's (DOT) Research and Special Programs Administration (RSPA) developed a new risk management framework that is designed to be used by all parties (e.g., shippers, carriers, etc.) including DOT personnel, to help in systematically evaluating the risks of hazardous material transport operations. In addition, the framework can also be used to assist in implementing activities that reduce the risks associated with hazardous materials transport operations.

To develop the risk management framework and evaluate its real-world applicability, RSPA followed the five tasks described below:

- 1. Held a stakeholder exploratory meeting to introduce the idea of a new risk management framework and obtain feedback.
- 2. Evaluated existing risk management frameworks currently in use.¹
- 3. Developed a risk management framework.²
- 4. Convened a group of experts to provide feedback on the risk management framework.
- 5. Used case studies to evaluate the effectiveness of the framework.

This report presents the results of the Case Studies.

1.1 The Case Studies

To determine whether the risk management framework is flexible enough to be useful and more importantly, whether it can serve as an effective tool for encouraging the implementation of risk management strategies, RSPA chose to test the framework by applying it to a variety of existing programs. Stakeholders identified potential case studies in the exploratory meeting, and the expert panel further refined those recommendations. RSPA selected a few organizations to participate in this phase of the study. In choosing organizations to participate in the case studies, RSPA considered the following factors about an organization's program:

- Availability of data (e.g., history, results, mission statements);
- Existing and/or established industry/government programs;
- Voluntary participation; and
- Cross-party issues addressed (e.g., carriers and shippers).

After evaluating the above factors and taking into account stakeholder recommendations, RSPA chose the following three case studies:

- Case Study #1: Non-Accidental Release Program Administered by the Association of American Railroads
- Case Study #2: RSPA's Exemptions Program and the Regulated Medical Waste Exemptions
- Case Study #3 Risk Management Approaches used by Selected Members of the Trucking Industry

¹ Task 2 Report - Evaluate Current System. Prepared for DOT RSPA by ICF Consulting, April 24, 2000

² Risk Management Framework for Hazardous Materials Transport. Prepared for DOT RSPA by ICF Consulting, November 1, 2000

From these case studies, RSPA hopes to identify how adaptable the risk management framework is and also identify areas where the framework can be improved or modified. An additional benefit of these investigations is that they may reveal potential areas for improvement in the industry/government program to which the framework is being applied. The case studies were performed in sequential order. The risk management framework evolved and changed from case study to case study as we adopted specific case study recommendations.

1.2 The Risk Management Framework

A key goal of the risk management framework is to serve as a unifying structure and self-evaluation resource that will encourage and guide the voluntary use of risk assessment and risk management concepts and tools by the many disparate parties involved in transportation of hazardous materials. In this context, a "framework" is meant to describe an overall organizing structure that identifies the main elements of a process and explains how they fit together. The framework consists of three elements:

• *An Underlying Philosophy*

The philosophy for this framework is *action informed by analysis*. Analysis provides the information needed for decision-making and planning but does not by itself reduce risks. Risks are reduced by actions, and therefore action – informed by analysis – is the true cornerstone of effective risk management. Analysis should be driven by the need for information to feed into decision-making about what actions, if any, are appropriate.

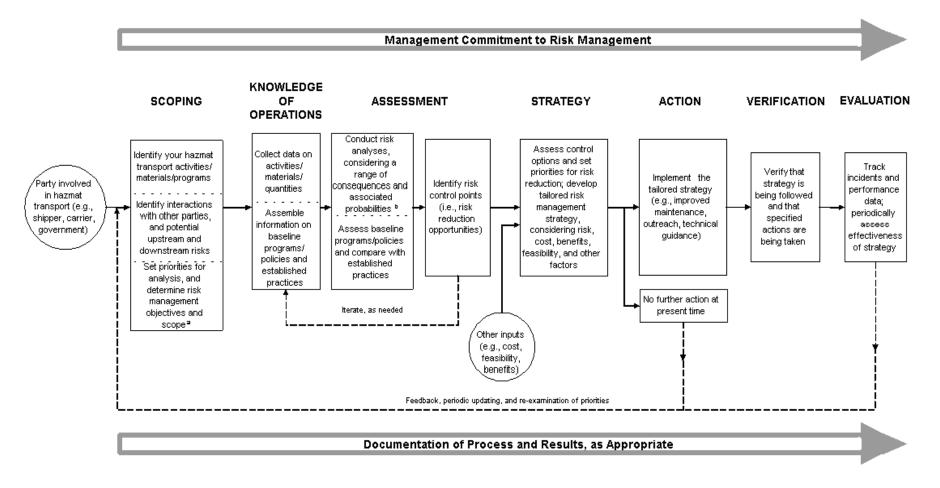
• Fundamental Principles

Seven principles in the framework will guide, at the broadest level, individual risk management decisions and actions. The seven principles are: 1) commitment; 2) culture; 3) partnership; 4) priority setting; 5) action; 6) continuous improvement; and 7) communication.

• A Generic Risk Management Approach

The framework includes a generic and stepwise approach to risk management for hazardous material transportation that can serve as the foundation for an organization's risk management program, or it can be applied in a more focused way to guide risk management analysis and implementation targeted to individual materials or operations. This generic approach consists of the following overlapping steps: 1) Scoping; 2) Knowledge of Operations; 3) Assessment; 4) Strategy; 5) Action; 6) Verification; and 7) Evaluation. In addition, the generic, stepwise approach requires establishing and maintaining management commitment and keeping appropriate documentation of analysis and actions. Exhibit 1 provides a flowchart that shows how the stepwise risk management approach operates and provides a brief explanation of each of the steps. These steps reflect the final recommendations from the case studies. In particular, some steps were reordered as a result of case study #1. In the description of case study #1 (Section 2), we have keep the original steps in the proposed framework step to show the reader how the framework changed before and after the case study.

Exhibit 1. A Generic, Stepwise Approach to Risk Management for Hazardous Materials Transportation



^a Scope can vary from extremely broad, such as addressing a company's entire hazardous materials transport activities, to very specific, such as targeted to a single material or transport route ^b Analyses can be qualitative or quantitative, and usually are partly both.

2. Case Study #1: The Non-Accidental Release Program Administered by the Association of American Railroads

2.1 Rationale for Selecting NAR Program

The trade association selected to participate in this case study is the Association of American Railroads (AAR). The AAR administers a hazardous material release-prevention program called Non-Accident Release (NAR) Program. RSPA chose the AAR's NAR Program because it has been quite successful in reducing the number of non-accident releases in the last few years and there was also a sufficient amount of data and documentation available for analysis. In addition, the NAR Program involves various players (e.g., carriers, shippers, regulators) and therefore cross-party issues are prevalent. Also, by applying the risk management system to a program administered by a trade association, instead of an individual company, we would reveal how truly flexible, adaptable and effective the framework is.

The AAR is a association that represents the North American railroad industry and advocates the interests of railroads in the public policy arena. AAR also works to make the rail industry safe, efficient, and productive by conducting and coordinating research (e.g., developing industry standards) and by facilitating the exchange of information between railroads, customers, and shippers.

2.2 Description of NAR Program

The AAR is concerned about NARs because they can indicate operational deficiencies that, if left unchecked, can lead to larger scale accidents or releases (see box for definition of NAR). Furthermore, NARs pose risks to the safety of employees and to the environment and also result in customer concerns. Finally, NARs can raise costs for the railroad industry since they lead to shipment delays, environmental clean-up fees, employee injuries, and in some cases evacuation events.

The U.S. NAR program was modeled after a very successful Canadian NAR Program, which resulted in a 32% decrease in tank car NARs throughout Canada between 1991 and 1995. In order to decrease the frequency of NARs in the U.S., the AAR established the U.S. NAR prevention program in 1995. The U.S. NAR prevention program is led by the AAR Haz Mat Committee, which is primarily comprised of railroad industry Haz Mat experts. This Committee also organizes Haz Mat handling training sessions.

The goal of the NAR Program is to reduce the frequency of NARs throughout North America by 25% by 1998 and by 50%_by the end of the 2000 (1995 is the base year). To reach this goal, an NAR Committee was established, a comprehensive outreach program was put

What is an NAR?

An NAR is defined as an unintentional release of hazardous material during transportation not caused by an accident or derailment. NARs consists of leaks, splashes, and other releases from improperly secured or defective valves, fittings, and tank shells, and also include venting of non-atmospheric gases from safety relief devices. The vast majority of reported NARs involve small quantities (less than 10 gallons) of vapor or liquid.

into place, and performance-tracking system was developed. The NAR Committee, which involves representatives from all involved parties, provides program direction, evaluates results, and assists in the development of guidance material. Exhibit 2 presents the major types of NAR Program activities currently in place. To be successful the NAR Program must raise awareness among all involved players and therefore the NAR Program includes shippers, carriers, car owners, trade associations, receivers, component suppliers and regulatory agencies; many of which are not member companies of the AAR. The effectiveness of the NAR program is to large extent dependent on the voluntary participation and

cooperation of many non-member companies. Thus, many of the activities in Exhibit 2 are designed to raise awareness and improve communication.

Exhibit 2. Types of NAR Program Activities

| Activity Category | Specific Activity |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Development of and participation in the NAR Committee |
| | NAR technical discussions and development of educational material |
| Raising Awareness | • Developing/distributing "Action Packages" to companies that experience |
| | NARs |
| | Workshops for unloaders and loaders |
| | Developing and sharing solutions to the NAR problems |
| Encouraging | Promoting proper securement and handling of tank cars carrying |
| Improvement | hazardous materials |
| | • Awards for shippers with the best performance (lowest freq. of NARs) |
| Communication of Results | Identifying shippers who exceed a specific NAR frequency threshold |
| Collecting and distributing NAR Data | Creating a data base of all NARs and tracking performance Analyzing and distributing data through "Action Packages" and at NAR Committee meetings |

One of the most important activities under the NAR Program is the development and distribution of Action Packages. These packages are essentially NAR performance reports that describe the type of NARs that occurred (e.g., commodity that leaked, where it leaked) and also contain information on how to prevent the reoccurrence of NARs. These reports are company specific and are sent directly to customers and companies, primarily shippers and car owners, who exceed a specific NAR frequency threshold on a quarterly basis. The Action Packages contain an accompanying letter requesting that the company take action to eliminate further NARs. Information on NARs is collected by analyzing the DOT 5800.1 hazardous material release forms³ and is supplemented with information from CHEMTREC ⁴, AAR inspection reports, and Canadian railroad reports.

For 4 years the NAR Program was very successful at reducing the frequency of NARs in the United States. In fact, from 1995 to 1998 a 30% reduction in the frequency of NARs was achieved. However, recently the reduction in frequency of NARs has leveled off and in 1999 a slight increase in the number of NARs was evident. It is important to note that reduction in NARs is not entirely attributed to the NAR program. Other factors such as technological innovations have also contributed to the reductions.

2.3 The NAR Program and the Proposed Risk Management Framework

2.3.1 Comparison of the NAR Program with the Proposed Framework's Philosophy

The NAR Program does not have a formal "Underlying Philosophy" as described in the risk management framework, but its overall mission or strategy can be viewed in a similar way. The NAR

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³ Railroads (and all other transporters of hazardous materials) are required to report to the U.S DOT any incident involving the release of hazardous waste or unintentional release of a hazardous material during transportation. These reports filed with U.S. DOT are called DOT5800.1 reports.

⁴ CHEMTREC is the chemical industry's emergency response information center.

Program's mission is to prevent the occurrence of NARs through information collection-distribution programs. Developing extensive awareness campaigns drives the program. Like the framework's *action informed by analysis*, the NAR Program's mission or strategy includes both an action and an analysis element. In the context of the proposed framework, the analysis element translates into the extensive NAR data collection efforts taking place; these efforts include, compilation of DOT 5800.1 reports, analysis of NAR frequency by company, and trend analyses. As for the action element, the NAR Program does include activities, like the distribution of Action Packages and other informational material, which can be considered action. The goal of the program is to motivate participants to act and reduce NARs.

However, the framework's underlying philosophy does focus more on an analysis of risks and contributing factors than on information collection. The information collection activities in the NAR program are based on collecting data from events that have already occurred (e.g., NARs occurring in the past year) instead of on data gathered from individual analyses to determine the potential or risk of an incident or an NAR in the future.

2.3.2 Comparison of the NAR Program with the Proposed Framework's Principles

This section focuses on how the major NAR Program elements tie into the risk management framework principles that were introduced in Section 1.2. Exhibit 3 provides a brief description of each of the framework principles and the equivalent or similar NAR element, if one exists, under the NAR Program. The last column provides some brief statements on how well each framework principle ties into each of the NAR program elements.

In general, the framework principles appear broad enough to incorporate a wide variety of equivalent or semi-equivalent activities. One of the more important differences to note is that the NAR Program interprets prioritization in a more limited way than is recommended by the framework. The NAR Program uses prioritization to determine which parties will be sent Action Packages, but this is more of a threshold determination. With the recent leveling in the number of NARs, it will be interesting to see how additional prioritizations may be determined by the NAR Program. Finally, it seems that a more thorough investigation of priorities takes place within the AAR and outside of the NAR Program to determine which safety issues affecting carriers should be addressed. It is apparent that the AAR has established the NAR Program as one of its priorities with derailment prevention as its top priority.

Exhibit 3. Comparison of Framework Principles and the NAR Program Activities/Elements

| Framework Principle | Description | Applicable NAR Program Activities | Comments |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Commitment | A tangible and visible commitment, including resources from management and the work force to reduce risks. Incentives should be provided to reduce risks. | A commitment to form and participate in the NAR Committee which directs the NAR Program. Awards are given to shippers who have a low frequency of NARs. | NAR activities are equivalent to this framework principle. However, effectiveness of the NAR Program may be limited since preventive actions must be carried out by non-AAR companies and the NAR Committee is a voluntary effort with limited allocated resources. |
| Culture | Existence of "risk reduction culture" in daily operations. This includes incorporating risk considerations into management systems such as recordkeeping, training, and performance evaluation. | Existence of the NAR Program demonstrates a focus on risk reduction. | The AAR conducts a wide range of activities, and the priority given to the NAR Program indicates that the AAR has established a risk reduction culture. |
| Action | Concrete actions specific to your operations that are specifically aimed at reducing risk. | Development and distribution of Action Packages and guidance documents. The AAR Haz Mat Committee develops workshops and training sessions on the safe transport of Haz Mat. | Action Packages do represent a good example of NAR program risk reducing actions. Specific risk reduction actions should also take place at the company level. |
| Prioritization | Establishment of priorities, based on analysis, to address worst risks first. | Priorities, and subsequent actions, are based on whether the numbers of NARs have exceeded a threshold. Companies receiving Action Packages may have their own prioritization efforts in place to deal with NARs. | A decision has been made by the AAR to reduce NARs and institute the NAR Program. Prioritization efforts are based on number of NARs Thresholds for number of accidents are set to determine which companies to include in the program. |
| Continuous Improvement | Demonstrated efforts at improving risk management and efficiency through commitment, self-evaluation, and an overall willingness to change and adapt as necessary. | The NAR Program goal is to reduce the number of NARs by 25% within a 3-year period and by 50% within 5 years from the start of the program. Awards for shippers with superior programs. | A concerted push to reach a goal or accomplish a mission, like the NAR program goal, can demonstrate efforts towards continuous improvement. Additional feedback from recipients of action packages would strengthen continuous improvement efforts. |
| Communication | Awareness, among all parties involved in risk management (e.g., employees, customers, etc.), of their role in taking steps to reduce risk. | Development and distribution of Action Packages and guidance documents; providing information on NAR prevention methods to all parties. Increasing awareness among all parties is crux of the entire NAR Program. | Many of the NAR program elements or activities are good examples of a strong program emphasis on communication. Unique to this program is that fact that customers (e.g., shippers) are provided with risk reduction information for NARs. |

2.3.3 Comparison of the NAR Program with the Proposed Framework's Generic, Stepwise Risk Management Approach

The Framework's Stepwise Risk Management Approach (the Approach) from RSPA was developed to be flexible enough to be applied to a broad range of management situations and can even serve as the foundation for a company's organization overall risk management program. Alternatively, it can be applied in a more focused way to guide a risk management analysis and implementation targeted at a single risk operation. Exhibit 4 provides a flowchart that describes how the Approach operates. The flowchart in Exhibit 4 also provides a brief explanation of each step.

The discussion that follows centers on how the Approach for hazardous material transportation ties into or complements the NAR Program. Because the Approach is a sequential and repeating process that is comprehensive in nature, it is more useful to view and study the NAR Program in a similar fashion and consider all its parts/elements from beginning to end. Exhibit 5 presents a flow chart that diagrams the flow of information and the order of activities that take place within the NAR Program. It is important to note that Exhibit 5 shows two different sets of linked activities occurring at two different places. The upper set of flowchart elements (above dotted line "Occurring within AAR") describes the information flow that occurs primarily within AAR organization. The lower set of flowchart elements (below the dotted line) describes the ideal sequence of activities that take place within the company that has received an Action Package from AAR (see top, thin, arrow exiting the "Action" box). This set of generalized, company-specific steps may not apply to all companies.

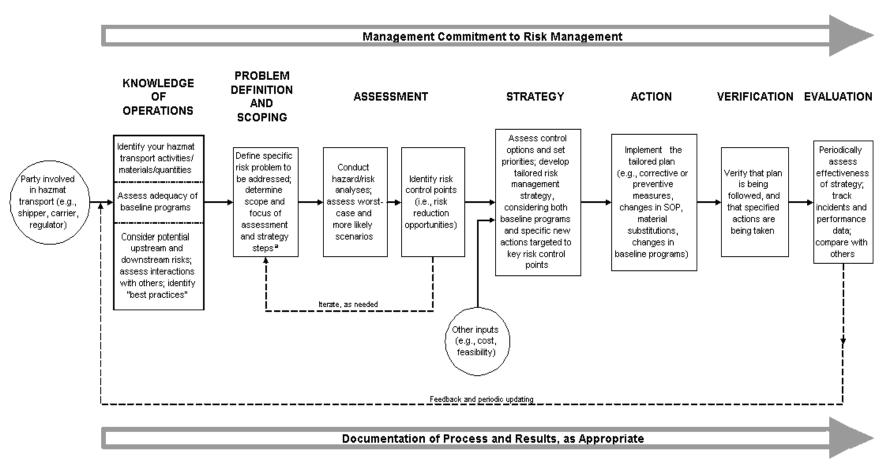
To see the relationship between the NAR Program and the Approach, we have categorized each of NAR program activities or elements in a manner similar to the steps found in the Approach presented in Exhibit 4. There are arrows connecting the Approach steps to specific NAR Program steps. It is most effective to view both Exhibits 4 and 5 next to each other.

2.3.4 Observations

The following sections lists some of the key observations that can be made as a result of comparing the NAR program to the Approach.

- Control Points are places where control can be applied to prevent, eliminate, or reduce risk. Within the NAR Program there are some places that could be considered risk control points. For the most part these places occur at the company and not within the NAR Program at the AAR level. These places or events may include: 1) securement of tank car fittings; 2) protection of tank car valves with dome cover; 3) design of vents; 4) loading procedures; and 5) management commitment. Risk control points at the AAR level include decisions as to when to provide Action Packages, what action steps to recommend to the company, and the follow-up activities with the companies.
- Maintaining Appropriate Documentation of all analyses, data, results, decisions and any other information related to an organization's risk management system allows an organization and others to learn from experience. In other words, successes or failures can be traced back to decisions or actions when proper documentation is available. The NAR Program appears to contain several activities that fall under the framework's Appropriate Documentation step. For example, annual reports are published by the AAR that summarize the results of the NAR Program and its effectiveness in reducing the frequency of NARs.

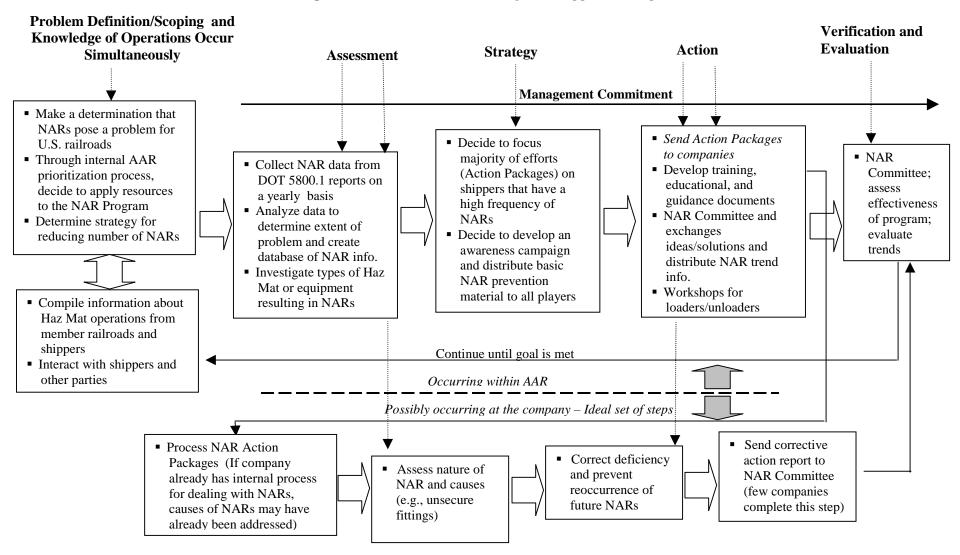
Exhibit 4. A Proposed Generic, Stepwise Approach to Risk Management for Hazardous Materials Transportation



^a Scope can vary from extremely broad, such as addressing a company's entire hazardous materials transport activities, to very specific, such as targeted to a single material or transport route

Exhibit 5. The NAR Program Flowchart and Equivalent Proposed Generic, Approach Steps

Possible Equivalent or Similar Risk Management Approach Steps



- Both the Approach and the NAR Program seem to have a sequential, stepwise approach with the end result consisting of some form of overall evaluation. This demonstrates the flexibility of the framework to encompass variations in the way the evaluation step is applied.
- Both systems have an information feedback loop that promotes continual improvement until the goal or mission is achieved.
- The problem definition and scoping step play fundamentally different roles in the NAR Program and the Approach. In the NAR Program, the problem was identified and defined prior to initiating the program. The Approach's problem definition and scoping step comes after assessment of baseline programs and is also tied to an assessment of risks. In other words, the results of an assessment narrow down the problem.
- Unlike the generic, stepwise approach there is not a significant verification step in the NAR Program. Companies are requested to comply with the guidance included in the Action Packages, but there is little activity of the NAR Committee to follow-up with companies to verify that action has been taken. There is more of an indirect method of verification within the NAR Program that consists of tracking those companies that are continually above the NARs frequency threshold. Those companies above the threshold may not be taking sufficient corrective action.
- The risk management framework suggests a structured analysis of risks is generally appropriate. The NAR Program is based solely on frequency of release. This is a simple yet structured approach to prioritizing and characterizing risk which is consistent with the broad risk management framework. A more comprehensive risk assessment step could focus on other factors (e.g., chemical/size/impact of release) which prioritize the risk from the NARs or could focus on comparisons of the risk of NARs with the risk of derailment. It is possible that the NAR Program does not include a more complex risk assessment step because additional complexity is not needed or perhaps there are limited resources available. Comprehensive risk assessments are resource intensive.
- The Approach requires a certain level of command and control to take steps to minimize risk. In other words, if deficiencies or risks are identified, there is chain of players that can act to reduce those risks or deficiencies. Within the NAR Program, the shipping companies take the operational corrective actions primarily and the NAR Committee provides Action Plan recommendations when warranted. When a variety of other players or organizations are involved, the level of complexity increases and effectively implementing the program may prove more challenging.

2.4 Conclusions

The conclusions are presented as responses to three questions.

2.4.1 What are Differences and Similarities Between the Proposed Risk Management Framework and the NAR Program?

The Risk Management Framework (including philosophy, principles and Approach) and the NAR Program do share some important similarities. Both systems ultimately have the goal of reducing the probabilities that accidents will occur. This translates into reducing the risk associated with hazardous material transport. Also, there are some similar activities, steps, and principles that are found in both the framework and the NAR Program. Though, the NAR Program and participating companies may not refer to its steps or activities in the same manner as the Risk Management Framework, studying the activities reveals that the basic goal is similar to the goals described in framework.

However there are a few differences between the framework and the NAR Program that are worth discussing. The framework places more emphasis on risk assessment activities than the NAR program. This is not surprising because the framework is in fact more of a risk management system than the NAR program which places a greater emphasis on post incident analysis and performance tracking. The NAR Program consists of analysis and actions by the AAR and the companies. Although by themselves, the AAR and the companies may not need to follow all of the steps in the framework, together they address the steps to varying degrees. Also, the risk reduction culture is likely mixed; because so many outside parties are involved.

2.4.2 Did the Proposed Risk Management Framework Prove to be Flexible and Adaptable?

For the most part, the Risk Management Framework did show sufficient, inherent flexibility to be adapted to the NAR Program. First, the framework includes many elements that are to some degree or other are found in many management systems, including incident prevention programs like the NAR. Second, the framework principles and steps are defined in broad enough terms to allow comparison or tie ins with the discrete steps from other programs. This is particularly noteworthy because the NAR Program operates on two levels, the analysis and actions by the NAR Committee and the analysis and actions by the company to correct non-accidental releases. Both levels are represented in the risk management framework. Finally, the Approach is sequenced in such a manner that it lends itself for adaptation to other systems that are based on logical sequence of steps.

Though the framework contained some elements of flexibility, there were other important areas where the framework did not complement or adapt well to the NAR Program. The following is a list describing some of the less flexible components of the framework.

- Risk control points in the framework can apply to both organizational programs (AAR involvement in NAR Program) as well as to systems that have a true operations component (shipper involvement in NAR Program). It is more difficult to apply the framework to organizational programs because potential control points become less easy to measure and gauge.
- The framework needs to be broad enough to encompass different levels of analysis and actions given various cost and resource constraints.
- The framework does not specifically mention that the steps of the framework can be followed consecutively on both an organizational level and an operational level.
- The sequence of the first two steps in framework, *Knowledge of Operations* and *Problem Definition and Scoping*, does not seem to coincide with the steps taking place in the NAR Program. Within the NAR Program there does not seem to be a clear distinction between the two steps and it is very possible that in fact the *Problem Definition and Scoping* step comes before *Knowledge of Operations*. This difference may indicate that the framework has to be modified to more accurately represent a logical, stepwise approach.
 - 2.4.3 Did the Proposed Risk Management Framework Help to Structure Improvements to the NAR Program?

As a result of studying the NAR Program and comparing it to the Risk Management Framework, a few recommendations for improving the NAR Program can be made. The following list briefly describes these recommendations:

- The NAR Program operates on two levels, the analysis and actions by the NAR Committee and the analysis and actions by the company to correct non-accidental releases. Both levels are represented in the risk management framework. The challenge is for the NAR Committee to work cooperatively with the shipper/carrier (e.g., share information on risk management and provide feedback loops to evaluate and improve the current program). For example, a more comprehensive verification step should be included to determine whether players (e.g., shippers, carriers) are following the guidance provided in the Action Packages and taking concrete steps to prevent the reoccurrence of NARs.
- It may be beneficial to consider addition risk factors in the NAR Program to build on the existing risk assessment screening based on frequency. For example, characterizing materials transported into high, medium, and low categories, depending on the potential consequences of a release, type of chemical, and size of release.
- It may be prove beneficial to quantify or at least qualify the benefits accrued by preventing NARs through out the industry.
- Developing more extensive partnerships with all players would allow for a greater exchange of information. This partnership program could be modeled after the American Chemistry Council's successful Responsible Care Partners Program.
- It would be beneficial for all decisions made within the program and by the NAR Committee to be documented to track changes and learn when actions do not have the intended consequences.
- It may be useful to include a list of possible control points with Action Packages to help the shipper focus on the places that require the greatest attention.
- It would be beneficial to investigate other alternatives, besides the distribution of Action Packages, that may be effective in achieving further reductions in the frequency of NARs. For example, the NAR Program could learn more about certain shippers sectors (e.g., mining) that do not respond to the Action Packages as well as others and to develop strategies to have more targeted Action Packages.
- It would be beneficial to identify why non-accidental releases do not continue to drop, the NAR may need to obtain more feedback from the companies that receive the action plan.

3. Case Study # 2 - RSPA's Exemptions Program and the Regulated Medical Waste Exemption

3.1 Rationale for Selecting RSPA's Exemptions Program

RSPA chose to study its own Exemptions Program to evaluate how well the new risk management framework can be incorporated into its own processes to improve risk management efforts. In addition, applying the new risk management may reveal potential areas for risk management improvement within the Exemptions Program.

To present a more realistic picture of how the new risk management framework could be applied to RSPA's on-going exemption activities, this case study uses the events and actions that led to the approval of the regulated medical waste exemption to highlight specific elements or steps of the risk management framework. A wealth of information is available on this medical waste exemption and it provides a good example of the use of risk management principles. In addition, by focusing on this specific exemption approval process, a better understanding of the whole process can be obtained and the individual steps that occur throughout the exemption process can be more easily compared to the individual steps that occur within the risk management framework.

3.2 Description of RSPA's Exemptions Program

Exemptions provide alternatives to DOT's Hazardous Material Regulations (HMRs) and are used to provide relief from regulations when circumstances allow an exception to the rule. These circumstances involve requests to use other methods for transporting, packaging, or manufacturing hazardous materials besides the ones prescribed in the regulations. As a result, the Exemptions Program allows for implementation of new technologies and can result in more efficient transportation operations.

To obtain an exemption, an individual or organization must first submit an application to RSPA that identifies the specific DOT HMR that is being addressed and that fully describes the alternative method or system that is being proposed. At a minimum the exemption application must provide the following:

- Information describing all relevant shipping and incident experience;
- A statement identifying any increased risk to safety or property that may result if the exemption is granted and a description of the measures to be taken to address that risk; and
- *Either*, data or test results that proposed alternative will achieve a level of safety that is least equal to that required by the regulation from which the exemption is sought; *or*
- If a level of safety is not established by the regulations, an analysis that identifies each hazard, potential failure mode and the probability of its occurrence, and how the risk associated with each hazard or failure mode are controlled for the duration of an activity or life-cycle of a packaging.

For an exemption application to be approved the applicant must demonstrate either of the following (49 CFR 107.113):

• The proposed alternative will achieve a level of safety that is at least equivalent to the level of safety achieved in the applicable HMRs; or

• In cases where the HMRs do not establish a level of safety, the proposed alternative is consistent with the public interest and will adequately protect against the risks to life and property inherent in the transportation of hazardous materials in commerce.

The analysis that must be performed (by the applicant) to meet either of the above criteria is typically referred to as a safety analysis. RSPA requires all applications for exemptions to be accompanied by a safety analysis. The safety analyses, which accompany exemption applications, vary greatly, from more in-depth risk assessments to more simple performance investigations.

Applications are then evaluated by RSPA, and a determination is made whether the applicant has met either of the criteria. During the evaluation process RSPA will publish a notice in the Federal Register and make publicly available all documents relevant to the exemption application. If additional information is needed to properly evaluate the proposed alternative, RSPA can request that the applicant submit additional information. All exemptions are granted (or not) on a case-by-case basis. If a determination is made that an equivalent level of safety has been met, RSPA will grant the exemption. In some cases RSPA may grant the exemption, but impose additional provisions or conditions. As is the case with the Regulated Medical Waste Exemption, organizations other than the original applicant can apply for the same exemption and become parties to the exemption.

3.3 The Regulated Medical Waste Bulk Packaging and Transport Exemption

Regulated Medical Waste Exemptions are exemplified by two different Exemptions, #10821 and #10826, each of them addressing a slightly different set of HMRs. Exemption #10821 exempts applicants from the following DOT HMRs:

- 49 CFR 172.101 entry in Columns (8) (b) and (8) (c) for Regulated Medical Waste; and
- 49 CFR 173.197 where non-DOT specification packaging is defined and authorized.

Exemption #10826 was issued in 1993, and it exempts parties from the regulations listed above plus the following:

• 49 CFR 171.8 specific definitions found in the chapter titled, "Definitions and Abbreviations."

Essentially, the Exemptions authorize the transportation in commerce of regulated medical waste, in a non-DOT specification packaging consisting of a bulk outer packaging and non-bulk inner packagings that conform to certain provisions outlined in the Exemption approval itself. It is important to note that the Regulated Medical Waste Exemption provides no relief from any HMR besides the ones specifically stated on the Exemption approval form itself.

In order to tie in and compare the activities that took place during the evaluation process of the Regulated Medical Waste Exemption to the elements that make up the proposed risk management framework, it is necessary to describe how this particular Exemption came about and what actions RSPA and industries took. In addition, describing these events will shed light on how the exemption application and evaluation process takes place.

In response to a variety of high-profile incidents involving the mismanagement of medical waste in the early 80's, Congress passed the Medical Waste Tracking Act of 1988. This act required EPA to promulgate regulations to list and track various types of medical waste. In cooperation with EPA, RSPA, in 1991, modified the Hazardous Materials Table in 49 CFR 172.101 to include as two new items in the listing of proper shipping names, the items infectious substance and regulated medical waste (RMW).

Prior to 1991, RSPA regulated etiological agents and required this material to be packaged in quantities less than 4 liters. The new packaging requirements for infectious substance and regulated medical waste were similarly proposed to authorize only non-bulk packaging (less than 119 gallons).

After the new regulations were promulgated, but before the effective implementation date, RSPA received exemption applications from several waste haulers who were seeking authority to use bulk size packaging to transport RMW. Two distinct types of bulk packaging were proposed. Some companies had developed wheeled polyethylene carts of more than 119 gallons capacity for use in hospitals. Other companies had been using steel roll-off containers of several cubic yard capacity to transport RMW. The applications for exemption for both types of bulk packaging included the concept of dual packaging, in that the outer packaging of bulk size would contain a variety of inner packaging (e.g., plastic film bags, boxes or pails) that would contain the medical waste. The outer packaging was intended for decontamination and reuse, but none of the inner packaging would be emptied or reused prior to treatment and disposal. All the exemption applications claimed that their proposed packaging met an equivalent level of safety to that prescribed by the HMR's.

After careful evaluation of each application with supporting material and public comments, RSPA approved several of the exemptions for both types of bulk packaging for RMW. RSPA accepted the concept of dual packaging as meeting the requirement the exemption achieves a level of safety at least equal to the required by the HMR. In evaluating the exemption, RSPA conducted the following activities:

- Requested a demonstration from the applicants to show how the waste handler (i.e., Medex Inc. and BFI) handles, transports, and cleans the bulk containers that are used to transport regulated medical waste.
- Obtained additional information from the waste handler and actively soliciting information from the waste handler's customers regarding the packaging systems used.
- Thoroughly assessed all evidence provided by the applicant to determine if an equivalent level of safety has been met.
- Evaluated the risk/safety assessment provided by the applicant.
- Emphasized the need for a feedback loop to evaluate performance of alternative packaging.

A few years later, RSPA began receiving complaints from state public health and environmental agencies regarding the problems they were encountering with the same RMW bulk packaging systems that had been approved for use via the previously approved exemption. Some states claimed that the bulk packaging systems were not effective in properly containing RMW since on several occasions blood and other RMW fluids were seen flowing out of the outer packaging/containers. RSPA followed up on the complaints and began a compliance investigation. The investigation revealed that in some cases the RMW was not being properly handled or transported. Specifically, RSPA found out that some waste carriers that had received the exemption had proceeded to hire poorly trained subcontractors to pick-up the carts and containers, haul them, and dispose of the RMW. Additionally, RSPA determined that the hospitals generating the RMW had not properly trained their own staff on how to handle RMW. The combination of both parties not providing adequate training, resulted in the mishandling of the inner packages containing RMW and the release of potentially dangerous RMW fluids.

To correct the apparent problems, RSPA evaluated the entire RMW generation, packaging, and transportation system. From this evaluation, RSPA identified key elements or "control points" that both carrier and the shipper could focus on to reduce hazards to the themselves and to the public. These control points included the following:

- Establishing clear responsibility on the shipper (e.g., hospitals) for the RMW that they generate;
- Requiring appropriate training for all handlers and haulers;
- Verification of RMW handoffs between the parties involved; and
- Other activities/precautions.

RSPA met with all the stakeholders (e.g., carriers, shippers, state representatives, etc.) and presented its findings and recommendations. With some input from the stakeholders, RSPA then moved to significantly revise the RMW Exemptions in order prevent any further public health threats. All parties to the exemptions then had to comply with new requirements described in the revised exemptions.

Like all other applicants that have received exemptions, exemption holders must submit an application every two years to RSPA to renew their exemptions. Typically, in these renewal applications, applicants self-certify that the alternative packaging system or technology is still performing and will continue to perform adequately, thereby maintaining an equivalent level of safety. In some cases, a third party may be called in to validate the claims of adequate performance made by the applicant. Since the original application for Exemption #10826 was filed, several other companies involved in the medical waste hauling business have applied and were granted the exemption through party status. These companies, parties to the exemption, must also submit a safety analysis and must meet the same exemption standards. To provide greater control over requirements, RSPA made a policy decision to discontinue party status on RMW Exemptions with the revised Exemptions, and each are now written and handled individually.

3.4 The Exemptions Program and the Risk Management Framework

3.4.1 Comparison of the Exemptions Program to the Proposed Risk Management Framework's Philosophy

RSPA's Exemptions Program has two goals that combined can be viewed as an "Underlying Philosophy," as described in the risk management framework. The Exemptions Program's goals are:

- 1) Prevent the release of hazardous materials during transportation to protect the public; and
- 2) Exemptions are granted only when an "equivalent level of safety" is reached by the proposed alternative.

These goals are more specific than the proposed framework's *action informed by analysis* (Section 1.2) and are understandably more focused and performance-based. There are some similarities between RSPA's second goal and the proposed framework's philosophy. Specifically, to achieve RSPA's second goal it is necessary that the applicant perform a comprehensive safety analysis. The safety analysis attempts to demonstrate that all aspects of the proposed alternative achieve a level of safety that is comparable to that prescribed in the applicable HMRs. The applicant then submits the safety *analysis*, along with all other supporting documents, to RSPA, which then makes the final determination or takes an *action*. In other words, the second goal does contain an element of *action informed by analysis*. This action typically entails granting or denying the exemption request, imposing additional provisions on the applicant, or requesting that the applicant submit additional information. In addition, the framework's philosophy stresses the importance of proactive efforts for managing risk. The Exemptions Program in a way contains a similar emphasis in that the proposed alternative must be approved *before* a party can use the alternative. This proactive effort prevents parties from using alternatives that do achieve an equivalent level of risk reduction.

3.4.2 Comparison of the Exemptions Program to the Proposed Risk Management Framework's Principles

The following section focuses on how the major elements or activities of RSPA's Exemptions Program tie into the proposed risk management framework principles that were listed in Section 1.2. In some cases, some of the activities or events that occurred during the RMW Exemption application and evaluation process are used to investigate the consistency with the risk management framework's principles. Though the Exemptions Program is administered by RSPA who ultimately makes the final determination, applicants pursuing an exemption must perform a significant amount of work to obtain the exemption and to maintain it. Therefore, to fully investigate the Exemptions Program and its relationship to risk management framework principles it is necessary to include a variety of applicant, or industry, activities in this comparison.

Exhibit 6 provides a brief description of each of the framework principles and also shows the equivalent or semi-equivalent element or activity performed by either RSPA or the applicant. To identify which organization (RSPA or the Applicant) is performing or responsible for a certain activity or element, each of the listed activities appearing in the column titled "Similar or Equivalent Exemptions Program Activities/Elements" is shown in either *italics* or **grey** color. Activities performed by RSPA are shown in a **grey** font and activities usually performed by the applicant are shown in *italics*. In some cases neither the applicant nor RSPA perform a truly comparable activity. The final column titled "Comments" provides some brief statements on how well each of Framework Principles ties into each of the activities or elements listed in the previous column.

In general, the proposed framework principles emphasize risk identification and risk reduction more than many of the activities taking place under the Exemptions Program that are performed either by RSPA or the applicant. These differences in emphasis are more likely due to the different nature and focus of the two programs, rather than deficiencies in the activities/elements in either the proposed framework or the Exemptions Program. Because the proposed framework principles rely so heavily on the theme of risk reduction, it appears that they may not always tie as well into activities that do not contain an equivalent emphasis on risk reduction. Out of necessity, the Exemptions Program is quite prescriptive in the sense that there are very clear guidelines for performing most of the activities. On the other hand, the framework principles allow for a wide variety of activities to take place as long as they achieve the desired result of somehow reducing risk.

Exhibit 6. Comparison of Proposed Framework Principles and RSPA or Applicant Activities

KEY: Grey Color = Performed by RSPA *Italics* = Performed by Exemption Applicant

| Framework Principle | Description | Applicable Exemptions Program Activities/Elements | Comments |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Commitment | A tangible and visible commitment, including resources from management and the work force, to reduce risks. Incentives should be provided to reduce risks. | RSPA's overall mandate is to prevent the release of hazardous materials during transportation, thereby increasing public safety Applicants must certify when first applying that the proposed alternative is safe and will perform adequately. Upon renewal, safe performance to-date is certified. For many exemptions, including the Regulated Medical Waste Exemption, applicants must provide resources for training personnel which in turn reduces risk. | Some similarities are apparent primarily in RSPA's mandate. In order to fulfill this mandate, RSPA must provide resources to a variety of efforts aimed at managing or controlling risk, such as the Exemptions Program. Providing training can also be viewed as commitment to reduce risks. The applicant shows commitment to risk reduction by analyzing the safety of the alternative and committing to follow exemption conditions. |
| Culture | Existence of "risk reduction culture" in daily operations. This includes incorporating risk considerations into management systems such as recordkeeping, training, and performance evaluation. | RSPA is building a "risk reduction culture" and in general, risk management plays an important part in decision making. | Through the safety analysis and exemption conditions, RSPA attempts to strengthen the risk reduction culture of the applicant. |
| Partnership | Teaming up with all parties involved in a hazardous materials transport chain (e.g., shipper, package manufacturer, carrier, customer) is the most effective way to manage risks. Risk management is built on interaction among all the parties. | RSPA works together with applicants throughout the exemption evaluation process. RSPA requests additional information and is in frequent contact with the applicant and sometimes others (e.g., customers working with applicants). Applicants often provide large amounts of information to RSPA for them to evaluate. | There does not seem to be any major issues between RSPA and the applicant. It is in the applicant's favor to seek a loose partnership with RSPA during the application process. |
| Prioritization | Establishment of priorities, based on analysis, to address worst risks first. Performed when resources for managing risks are limited | RSPA receives many requests for exemptions. RSPA addresses them on a first come, first serve basis except for emergency exemptions (e.g., lives directly at stake) which are handled immediately. | Generally, the Exemptions Program does not use risk to prioritize which exemptions to process first. |
| Action | Concrete actions specific to your operations that are specifically aimed at reducing risk. | Granting the exemption. Developing conditions or provisions to go along with the exemption. Developing an alternative technology and system (e.g., | Together, RSPA and the applicant take actions to maintain public safety. |

| Framework Principle | Description | Applicable Exemptions Program Activities/Elements | Comments |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | bulk packaging and implementing systems for medical waste) that meets or exceeds the prescribed level of safety and therefore reduces risk to a certain level. | |
| Continuous Improvement | Demonstrated efforts at improving risk management and efficiency through commitment, self-evaluation, and an overall willingness to change and adapt as necessary. | RSPA and the Exemptions Program monitor compliance with provisions and the adequacy of the provisions that accompany exemption approvals or renewals. If deficiencies are observed, the provisions/conditions are modified and improved. In a compliance review, RSPA obtained feedback from state public health and environmental agencies concerning the safety of the exemption. RSPA studied the issue, worked with the applicants, and revised the exemption to involve hospitals and other shippers. One of the conditions of the Regulated Medical Waste Exemption required BFI to install plastic liners inside their containers to prevent leaks. BFI and others have done so. Applicants develop a safety analysis that involves self-evaluation (e.g., critically studying the proposed alternative). Some modifications in the design or performance of the alternative may be needed after performing a safety analysis. Both RSPA and the applicant re-evaluate the exemption every two years. | RSPA will reexamine the exemption every two years to ensure that safety levels are maintained or improved. RSPA will continuously evaluate feedback on the exemption and revise the exemption as needed. The applicant must conduct a self-evaluation to ensure adequate levels of safety. |
| Communication | Awareness, among all parties involved in risk management (e.g., employees, customers) of their role in taking steps to reduce risk. | RSPA's Exemptions Program personnel are aware of the role they play in evaluating the safety analyses submitted by applicants and their role in making a determination whether an equivalent level of safety is reached by using a proposed alternative. Typically, it is required that all exemption applicants be trained on how to handle hazardous materials. In the first exemption, the applicant failed to communicate and train subcontractor personnel on medical safety and handling issues. Such issues needed to be communicated to RSPA. | In the Exemptions Program, RSPA and the applicant must communicate closely to build a common understanding of the safety issues. Within the applicant company, communications and implementation of the exemption provisions is an important responsibility of the applicant. Failure to communicate can lead to lower levels of safety. |

KEY: Grey Color = Performed by RSPA *Italics* = Performed by Exemption Applicant

3.4.3 Comparison of the Exemptions Program to the Proposed Framework's Generic, Stepwise Risk Management Approach

As discussed in Section 1.2 and Exhibit 1, the proposed framework's generic, stepwise risk management approach (the Approach) was developed to be flexible enough to be applied to a broad range of management situations and can even serve as the foundation for an organization's overall risk management program. Alternatively, it can be applied in a more focused way to guide risk management analysis and implementation targeted at a single risk operation.

The discussion that follows focuses on how the Approach ties into or complements the Exemptions Program. Because the Approach is a sequential and repeating process that is comprehensive in nature, it is more useful to view and study the Exemptions Program in a similar fashion and consider all its parts/elements from beginning to end. Exhibit 7 presents a flow chart that diagrams the flow of information and the order of activities that take place within the Exemptions Program. The flowchart should be followed from left to right.

To more clearly demonstrate in Exhibit 7 the relationship between the Exemptions Program and the Approach, we categorized each of the Exemptions Program activities or elements in a manner similar to the steps found in the Approach presented in Section 1.2 (Exhibit 1). Therefore, there are dotted arrows connecting the Approach steps to specific Exemptions Program steps. It is most effective to view both Exhibits 1 and 7 next to each other. Exhibit 7 uses a different font type and font color to identify which organization (RSPA or the Applicant) is performing a certain activity. Activities performed by RSPA are shown in grey, and activities performed by the exemption applicants are shown in *italics*.

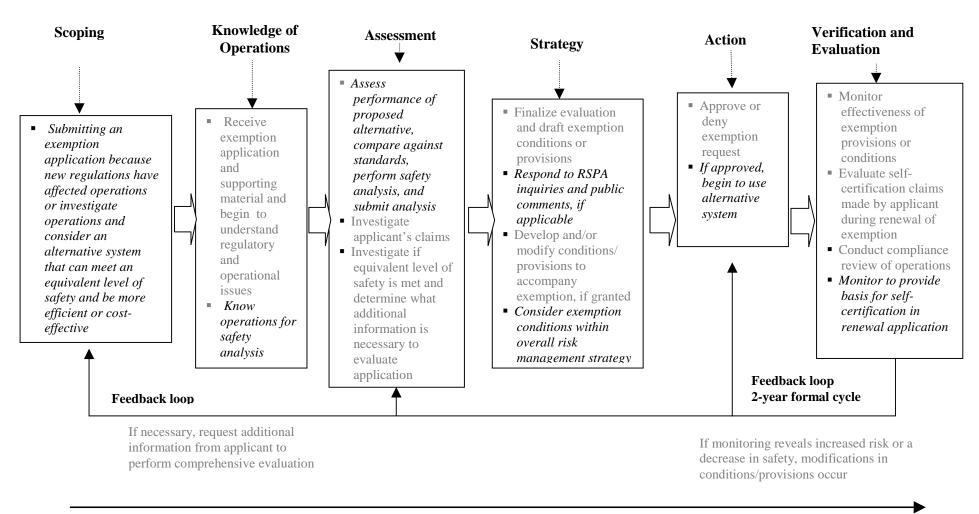
3.4.4 Observations

This section lists some of the key observations that can be made as a result of comparing the Exemptions Program to the Approach.

• Control Points are places where control can be applied to prevent, eliminate, or reduce risks. Within the Exemptions Program there are some places that could be considered risk control points. These places or events may include: 1) determination of equivalent safety; 2) development of a thorough safety analysis (e.g., addresses all safety elements discussed in the HMRs); 3) handoff points between shipper and carrier, 4) compliance with all exemption provisions/conditions; 5) monitoring and evaluation using feedback loops, and 6) acting to analyze the situation and take actions based on results of feedback.

Exhibit 7. The Exemptions Program Flowchart and Equivalent Proposed Stepwise, Generic Approach Steps

Possible Equivalent or Similar Risk Management Approach Steps



Maintain internal, RSPA decision check-off lists, filing all public and applicant correspondence, recordkeeping, etc.

Both the Approach and the Exemptions Program have a sequential, stepwise approach with the end result consisting of some form of evaluation/verification and a connecting feedback loop. In the Exemptions Program the feedback loop demonstrates how information gained from monitoring and evaluating exemption conditions can be used to continually modify an approach that is used to reduce risk. These last two steps in the Exemptions Program represent very good examples of "feedback, periodic updating, and reexamination of priorities" that is recommended in the Approach. The feedback loop in the Approach extends to the beginning of the flow diagram (see Exhibit 1). The goal achieved in both of processes is the same: through modifications, constantly improve efforts at reducing risk. In Exhibit

The Feedback Loop: A Real World Example

Upon receiving complaints from a state agency in 1997, RSPA proceeded to investigate allegations that packages of medical waste were not being handled correctly, resulting in fluid leakage from bulk transport containers. The investigation revealed that manufacturers of the medical waste (e.g., hospital shippers) were not properly handling the waste for the alternative packaging. RSPA understood the important role of the handoff between the hospital shippers and the carriers in the process. Thus, RSPA reevaluated the exemption and revised it to incorporate stringent requirements for the hospital shippers. The feedback loop enabled RSPA and the stakeholders to ensure the alternative packaging maintained public safety.

7, a shorter feedback loop is shown from Verification and Evaluation to Actions; this loop would be extended back to Scoping if RSPA found significant concerns during the 2-year application renewal.

- Maintaining Appropriate Documentation of all analyses, data, results, decisions and any other information related to an organization's risk management system allows an organization and others to learn from past experiences. In other words, successes or failures can be traced back to decisions or actions when proper documentation is available. It appears that almost through every step of the exemption evaluation process, RSPA, and most likely all other parties involved, maintain considerable documentation of decisions and investigations. This is evidenced by the large quantity of documentation that is kept for each exemption application in DOT's public reading room. For example, while determining if an equivalent level of safety has been achieved, RSPA uses and completes a checklist to make sure that all factors have been adequately addressed. All of these recordkeeping requirements are in place primarily to make the exemption application evaluation process as transparent as possible and to allow the public and the applicant to clearly understand why certain decisions were made. Because the Exemptions Program is part of a regulatory process, extensive documentation is required.
- The Approach and the exemption application process do converge very well under the Assessment, Strategy, Action, Verification, and Evaluation steps. The Assessment step in the exemptions process entails a safety analysis by the applicant and a thorough evaluation by RSPA. The safety analysis could be a complex quantitative risk analysis or could be a relatively simple comparative analysis. In either case, the safety analysis is comprehensive in nature and most importantly it addresses the issue of whether the alternative approach will in fact reduce risk to a necessary level. The assessment step is also connected to the Knowledge of Operations step via feedback loop. This feedback loop demonstrates that RSPA may request that the applicant provide additional information so a thorough evaluation can be completed. For example, during the regulated medical waste exemption evaluation, RSPA communicated with Medex, Inc. and requested additional information on a variety of topics including: 1) types of medical waste being loaded; 2) packaging surrounding the individual medical waste loads; 3) personnel exposure and safety; 4) performance tests of the bulk container being used, and 5) other topics.

3.5 Conclusions

The conclusions are presented as responses to two questions.

3.5.1 What Are the Major Differences and Similarities Between the Proposed Risk Management Framework and RSPA's Exemptions Program?

The proposed Risk Management Framework (including Philosophy, Principles, and Approach) and the Exemptions Program share many similarities. Both of these decision-making systems employ similar iterative processes (e.g., feedback loops) to improve the evaluation/assessment process and thereby manage risk more effectively. In addition, throughout the exemption evaluation (after the Assessment Step) process and beyond, RSPA does focus on its commitment to maintain an equivalent level of safety and protect the public from hazardous materials. This commitment is very similar to the Framework's emphasis on maintaining "Management Commitment to Risk Management." Finally, there is a variety of similar activities, steps, and principles that are found in both the proposed framework and the Exemption Program that were described earlier. For example, the proposed framework is a continuous process that can be applied over and over again to improve a particular risk management issue or to address a variety of risk-related problems. The exemptions approval/evaluation process occurs periodically for each type of proposed alternative and then modifications (e.g., provisions/conditions changed) may occur in the future. Initiating events for modification could be the two-year applicant renewal or a further technological component.

3.5.2 Did the Proposed Risk Management Framework Prove to be Flexible, Adaptable, and Useful?

Specific elements of the proposed risk management framework seem to adapt reasonably well to the particular areas of the Exemptions Program. First, the later steps of the Approach (the Assessment step and onward) seem to be slightly more adaptable to wider range of activities. In other words, these steps included enough sub-activities so that it was possible to find some common ground between the two systems. More importantly, many of the Approach steps and the framework principles contain useful recommendations within their descriptions that could be incorporated into the Exemptions Program to improve risk management efforts. For example, identifying control points within the application evaluation process and incorporating incentives into the exemption renewal process are two things that could possibly decrease the risk of improperly evaluating an alternative or using an alternative in an unsafe manner. Second, the proposed framework proved to be a useful tool in the sense that it requires the users of the proposed framework to critically analyze their decision-making or risk management model, like the Exemptions Program, and determine where risk management improvements, if applicable, can be made. Finally, the Exemptions Program operates on two levels, the analysis and actions by RSPA on the exemption and the analysis and actions by the applicant. Both levels are represented in the risk management framework. The challenge is for RSPA to communicate and work closely with the applicant (e.g., share information on risk issues and provide feedback loops to evaluate and improve the current exemption).

4. Case Study #3: Compilation of Risk Management Approaches Used by Selected Members of Trucking Industry

4.1 Rationale for Selecting and Methodology for Studying Risk Management Approaches

The trucking industry is an important sector for the transport of hazardous materials. Also, because the trucking industry is so diverse (e.g., size, geography, response level), it was crucial to test the risk management framework for this sector. There are many trucking companies in the U.S. that transport hazardous materials. To present a more realistic picture of how the proposed risk management framework could be applied to the trucking industry, ICF interviewed a few companies involved in the transport of hazardous materials by truck. The companies varied from large trucking companies that carry hazardous materials loads for many members of American Chemistry Council (ACC formally the Chemical Manufacturers Association) to insurance companies that strongly concern themselves with risk management of trucking companies. This case study forms a compilation or profile of the types of approaches to risk management used by these different companies (see Section 4.2). ICF then analyzed how this compilation of approaches outlined by the trucking companies compared with the proposed risk management framework (see Section 4.3). Conclusions for the case study are then presented (Section 4.4). Applying the proposed framework to a compilation of risk management systems used by trucking companies will help in determining how the proposed risk management framework can be used by other trucking companies to improve risk management efforts.

For this case study, the National Tank Truck Carriers, Inc. (NTTC) was helpful in providing various company contacts in the trucking industry. The companies including Miller Transportation, Groendyke, and Environmental Compliance Service have active risk management programs or have a strong interest in hazmat truck safety. They vary from large and medium sized trucking companies in the hazmat world to consulting firms that specialize in insurance issues surrounding the truck transport of hazardous materials. ICF then conducted telephone interviews with these companies. The company contacts were typically safety and risk managers.

To ascertain what risk management systems were currently being employed and how they are implemented, ICF posed the same scenario to each company. ICF asked each of the companies how they would address safety and risk concerns if they were to embark on carrying a new hazardous material that they had not carried before. For most companies, this scenario was frequently addressed. Then, ICF characterized their approaches to risk management and analyzed how this compilation of approaches outlined by the trucking companies compared with the proposed risk management framework. Although it is the nature of a case study to focus on an individual program or situation, one caution is that these comments and analyses are based on a small sample of contacts. We did not intend to represent the trucking industry as a whole.

4.2 Compilation of Risk Management Approaches

When thinking about managing the risk of transporting a new hazardous material, the trucking companies identified the following risk control points based on the staff's experience. ICF has categorized these control points into several topic areas that generally follow the steps in the RSPA risk management framework:

4.2.1 Understanding and Evaluating the Hazards and Risks

• **Properties of the Hazardous Material:** First and foremost, companies needed to understand the hazards of the product (e.g., toxicity, flammability, reactivity). Trucking companies may obtain such information from the shipper or from Materials Safety Data Sheets. Trucking companies look to see if they have transported materials with similar properties (e.g., carried common acids, but do not want to carry

hydrofluoric acid). The trucking companies will then check to see if their equipment is compatible with the hazardous materials (e.g., are stainless steel tanks sufficient?). Additionally, trucking companies will want to gain insights into proper handling and emergency response.

- **Process Review:** Some trucking companies formally conduct a process review of operations especially the areas where equipment, materials, and people come together. The review helps to examine risk issues in advance of commencing shipments. For example, one trucking company uses a team approach to conduct a "What If Analysis." Most of the time, less formal reviews are conducted and may only depend on an informal consideration of risk based on past experiences.
- **Decision to Not Carry Load:** For a variety of reasons, trucking companies will decide not to carry a new hazardous material. The most common reason is if they feel that carrying the load could endanger their employees. Additional reasons include if the hazardous material is highly toxic, poses significantly different hazards than typically handled, requires extensive capital investment in equipment, or requires unusual travel specifications (e.g., hauling cyanide up mountainous area requiring additional pushing by a bulldozer).

4.2.2 Addressing the Hazards

- Consignee Involvement in Risk Management: While transporting and loading activities are often examined in detail to control risk, the activities at the consignee site (e.g., unloading) are sometimes not addressed. Because often, the problem or spill occurs at the consignee site (e.g., hose rupture, mistaken tank, lack of protective equipment) many trucking companies have judged that one of the most critical risk control points is the lack of consignee involvement in risk management. To counter this risk area, there are several recommendations including communication and sharing of risk information, clarification of reduction measures, integrated procedures, site reviews and tours.
- Government Requirements for Handling: There are different regulatory requirements for handling different types of hazardous materials. Trucking companies will look at regulatory requirements from the U.S. Department of Transportation, Environmental Protection Agency, Occupational Safety and Health, and state and local agencies.
- Training Needs: Based on the hazards, trucking companies will investigate into whether their existing training programs cover the hazards. Additionally, trucking companies look outside for additional training resources from shippers and emergency response contractors (see below under shipper partnering and assessing emergency response). For example, before one trucking company began to carry hydrogen peroxide, all of the safety and operations personnel were trained in the hazards of the material, its stability, and how to calculate peroxide concentrations.
- Routing and Travel Time Issues: Trucking companies evaluate routing issues for transporting new hazardous materials and are particularly concerned about certain features including tunnels, proximity to schools, other sensitive and vulnerable facilities, or historically dangerous intersections or route segments. Some companies have their own routing policies to reduce risk including preference for multi-lane highways, travel only during daylight hours (e.g., reduce fatigue factor), and avoidance of rush hours.
- **Response Capability:** Most trucking companies will not have extensive response capability for large spills of highly hazardous/flammable substances. Trucking companies will look at their own capability and work with shippers or their response contractors to determine what other emergency response capability (e.g., specialists, equipment) is needed. Some trucking companies will establish contingency

arrangements with emergency response contractors while others have response contractors provide training for carrier staff.

- **Best Practices:** Many of the trucking companies do not seem to make use of a significant number of best/recommended practices. Although there is knowledge of various efforts (e.g., ACC Distribution Code, NTTC Manual of Recommendations), it is not clear how widespread these sources are used.
- Tank Cleaning: One trucking company judged that tank cleaning is a significant risk control point. Often in determining the risk in handling a product, the issues surrounding cleaning the tank and residual hazardous material are largely overlooked. Before handling the hazardous material, the trucking company should know how to clean the tank, who is responsible for cleaning the tank, and how to properly eliminate residuals and cleaning agents. This assessment is not in the ACC Distribution Code yet according to one trucking company, improper tank cleaning can represent hazards to persons and the environment.

4.2.3 Continuous Improvement and Evaluation

- **Test Loads:** After deciding to carry the load and managing risk from the new operation, some trucking companies have mechanisms for continuous improvement for risk reduction. One trucking company conducts test loads or field safety tests where safety coordinators and perhaps the shipper will examine all procedures in a test load and provide feedback to reduce risk.
- **Feedback Reports on Operations:** Additionally, some trucking companies complete customer service reports after they get back from delivering a load to the consignee (receiver of shipment). Recorded on the report is risk reduction-related information such as routing in the facility, locations of delivery points, and other safety-related information (e.g., confidence in consignee knowledge of product).
- Evaluating the Risk Management Program: Evaluation occurs both internally and externally. Insurance companies have conducted safety audits to characterize the risk of the company and to offer recommendation for risk reduction alternatives. Typically, a team of auditors includes representatives from safety, business, and management. Using a scoring system, such audits have helped to highlight strong and weak areas within a trucking company. Action plans will determine on a priority basis what needs to get fixed and a schedule. Although risk management should be proactive, an accident is probably still the lead factor in triggering an examination of risk.

4.2.4 Management Commitment

- General Commitment to Risk Management: Management commitment is a significant risk control point for the trucking industry. All trucking companies acknowledged the importance of commitment of senior company management to managing risk of hazmat transportation. According to risk and safety personnel, without such commitment, trucking companies will not take the time or invest the money to reduce risk. Companies examine the commitment by studying how duties are assigned, how risk is communicated, how risk might be incorporated into personnel reviews, the level of training on and documentation of risk reduction procedures and equipment.
- Partnering with Shippers and Others in Transport Process: A key risk reduction step in deciding whether to carry the hazardous material or to develop the necessary capability is to establish a cooperative relationship and exchange of information between the carrier and the shipper. Usually a safety or risk manager at the carrier will want to discuss extensively the hazardous material with the shipper. Partnership may take the form of getting information on hazards, coordinating training, understanding the

requirements for emergency response, cleaning the tanks, and loading/unloading practices. Some trucking companies will send drivers to the shipper to receive specific instructions. Although sometimes difficult, trucking companies will try to encourage consignee involvement in risk management process.

- Employee Empowerment: In some trucking companies, risk reduction is made part of the culture and daily operations. Employees are provided ways to recommend improvements to safety (also see continuous improvement). Additionally, in some companies, drivers are given the authority to stop operations if they have risk concerns. Some trucking companies have arrangements with shippers so that if the carrier does not feel that the consignee delivery point is safe, the carrier can either ask the shipper for immediate assistance and guidance on the concern or temporarily shutdown operations until further notice.
- Continual Focusing on Risk Management: Often the trucking operations become routine and staff may
 lose focus on detailed safety and risk reduction measures. Maintaining an interest while focusing on risk
 reduction requires a visible strategy and approach and an engaging way to continually convey the risk
 reduction culture.
- Accident Investigation: Accidents must be investigated. In some trucking companies, there is a threshold (e.g., damage/cleanup greater than \$50K) for more detailed investigation such as root cause analysis with presentation of results to executive staff. Some companies stated that although the investigation process may be strong, the process to verify that corrective actions are implemented may be weak.
- **Risk Management Documentation:** The level of current documentation greatly varies from company to company. A formal procedure for collecting and establishing documentation must be developed to properly document risk management. Each company needs to decide how much is adequate.
- Competing Interests: Sometimes, commitment to risk management competes with other company interests, specifically, the cost competitiveness of the market and the drive to enter into a new service delivery. Compliance with government regulations help to level the playing field by providing minimal standards (e.g., tanker design).
- Managing Risk at Different Size Companies: The procedure for risk management at small and large companies should be the same. The level of risk management should be reflective of the risk posed by the operations. In the insurance industry, risk management is generally recognized as good business.

4.3 Comparison of Risk Management Approaches with Proposed Risk Management Framework

In conversations with the trucking companies, all of the principles of the proposed risk management framework were mentioned in one way or another. These include the principles of commitment, partnership, priority setting, action, continuous improvement, culture, and communication. The principles of commitment and partnership were particularly emphasized. For example, the trucking companies said that partnership with the shippers is key to managing risk in the areas of understanding the hazards, training, operating procedures, and emergency response.

The proposed framework's generic, stepwise risk management approach was developed to be flexible enough to be applied to a broad range of management situations including those at trucking companies. The thought process of the trucking companies seemed to emphasize certain steps in the generic stepwise approach to risk management as described in Section 1.2 (see previous Exhibit 1). The following bullets

briefly describe how the trucking companies did or did not fit into each of the steps in the generic approach to risk management.

- **Scoping Step:** Because ICF posed a scenario to the trucking companies to consider, the scoping step was in a sense pre-defined, however, the trucking companies immediately assumed that all aspects of their operations were open to risk management.
- **Knowledge of Operations Step:** The trucking companies began to collect information focusing on their baseline programs (e.g., training, emergency response) and the adequacy of those baseline programs to manage the new risk posed by a new hazardous material. Research on best practices was not actively sought out specifically by the carriers except for making contacts with shippers who could convey best/recommended practices.
- **Risk Assessment Step:** Most trucking companies did not conduct a formal risk assessment using established methodologies (e.g., ACC Distribution Code). Instead, they focused on risky operations based on the general experience of the safety/risk staff at the trucking company or from concerns highlighted by the shipper. Insurance companies use an audit process with weighted scoring to identify particular areas of risk.
- Strategy and Action Steps: When areas to improve risk reduction are identified from the risk assessment step, the strategy and actions steps seem to be conducted together and are based largely on experience of the carrier or highly recommended by the shipper.
- **Verification Step:** This step is sometimes performed.
- Evaluation Step: The evaluation of a companies risk management program is conducted by an insurance company, but is less often conducted on a regular basis by the company.
- **Management Commitment:** For these companies, continuous management commitment is considered key and just good business practice.
- **Documentation:** Documentation of risk management is not typically emphasized or conducted sufficiently to create a historical record to prepare new staff.

4.4 Conclusions

The conclusions are presented as responses to two questions. As stated earlier, although it is the nature of a case study to focus on an individual program or situation, one caution is that these conclusions emerged based on comments from and an analysis based on a very small sample of contacts in the trucking industry. We did not intend to represent the trucking industry as a whole.

4.4.1 What Are the Major Differences and Similarities Between the Proposed Risk Management Framework and the Risk Management Approaches Used by Selected Trucking Companies?

In general, the risk management approaches by the trucking companies were consistent with the philosophy and process steps in the risk management framework. Certain areas such as management commitment is strongly emphasized in both the risk management framework as well as by the trucking companies. The risk management framework suggests a structured analysis of risks is generally appropriate. Most trucking companies conduct this analysis by depending more heavily on experience to identify and characterize risk. It is also possible that the trucking companies do not include a qualitative/quantitative risk assessment step because of limited resources or are not familiar with guidance provided by other organizations (e.g., ACC, NTTC). The proposed risk management framework employs an iterative process (e.g., feedback loops) to improve the evaluation/assessment process. As a general course, the trucking companies do not emphasize the iterative process of risk management.

4.4.2 Did the Proposed Risk Management Framework Prove to be Flexible, Adaptable, and Useful?

Specific elements of the proposed risk management framework seemed to adapt reasonably well to the particular risk management strategies used by trucking companies. The framework seemed to capture most, if not all of the risk management areas considered by the trucking companies. It also covered most, if not all of the risk control points and new risk control points can easily be added. The framework and the stepwise flowchart are easy to follow and generally not-intimidating. Also, the framework seems to be useful in providing a comprehensive structure for well-experienced and seasoned trucking staff with strong interests in risk management. For example, the risk assessment step could remind trucking companies to conduct the assessment. Also, a formalized risk reduction method may help to reduce the pressures of industry competition to conduct cursory risk management or ignore certain risk reduction steps. References to resources and tools in the risk management framework will help trucking companies who seem not to make full use of these references.

There were a few areas where the risk management framework could be improved. Some parts of the generic stepwise approach could further emphasize partnership and the need for team efforts for risk management. Also, because assessing risk and control points at trucking companies depend heavily on the experience of safety/risk/operations staff, the framework should build in more references to how experience can play a role in qualitative and quantitative risk assessments. Finally, distributing and encouraging the use of the RSPA's proposed risk management framework is a challenge because many trucking companies do not seem to make use of current resources such as best/recommended practices.

Overall, the proposed framework proved to be a useful tool by encouraging the trucking company contacts to perform a comprehensive evaluation of risk and to critically analyze their decision-making about better ways to manage risk.