SUGGESTED PILOT PROJECTS

Development of an Analytic Approach to Determine how the Environmental Protection Agency's Integrated Risk Information System is used by non EPA Decision Makers

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ENVIRON International Corporation
Arlington, Virginia

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Pilot Projects to Enhance the IRIS Use Experience

Executive Summary

The United States Environmental Protection Agency (EPA) contracted with ENVIRON International Corporation to develop an analytical approach to determine how the Integrated Risk Information System (IRIS) is used by non EPA decision makers. The approach developed and used by ENVIRON was to identify categories of IRIS customers and determine how representatives within the categories use IRIS. Information was collected in several ways but the primary method consisted of interviews with representative customers from nine different user categories. The customers interviewed characterized themselves as the most frequent users within their company, agency, academic program, trade association, or organization. Thus, the suggestions presented in this report are based on information collected from a small but highly significant sampling of IRIS customers.

This report is supplemented by a larger Findings Report, which describes the overall project and information collection process, presents general findings, and includes detailed descriptions of the nine formal interviews.

A primary goal of the interviews was to determine how the IRIS use experience could be improved. Interviewees were asked what type of services and information would be beneficial and how the service could best be provided. It is important to emphasize that the interviewees are frequent customers, who use IRIS in their every day work lives, and have similar education and training. For example, the frequent users interviewed typically have training in toxicology, chemistry and related scientific disciplines.

Frequent customers find IRIS easy to use and therefore are not in need of training. But, they uniformly expressed interest in having opportunities to interact with ORD staff to discuss issues and concerns that they believe are of mutual interest. Many users recommended that an institutionalized dialogue mechanism be established that would allow for two way communication. Customers feel a loyalty to IRIS and want to work with the Agency to enhance the value of a necessary and valuable product.

A dialogue mechanism would allow for two basic types of communication desired by frequent customers:

- The opportunity to describe to key Agency officials the importance and necessity of IRIS to the decision making process. Customers consistently stated they believe EPA must be unaware of how dependent they are upon IRIS, and how challenged they are in the absence of IRIS files on key chemicals.

- The opportunity to hear from Agency decision makers and scientists regarding the IRIS file development process. Customers seek two types of information: a better understanding of the federal government internal review and external peer review

process that is required; and the scientific questions that are under discussion as a file is developed and finalized.

All of the interviewees expressed interest in participating in a dialogue opportunity. However, there is clearly a sub set of customers who are more dependent on IRIS: state agencies and regulated parties, particularly companies that manufacture and use chemicals. These customers were adamant in their need to interact with the Agency on IRIS related concerns. Presently, discussions between ORD officials and industry representatives largely focus on specific chemicals. What is missing is the opportunity to have a higher level dialogue regarding the role of IRIS in decision making.

Frequent customers also expressed interest in further analysis regarding the use of IRIS as well as what occurs in the absence of an IRIS file. The customers interviewed have only a limited understanding on how IRIS is used by others and would like to have more documentation and case studies. For example, state agency risk assessors believe they could benefit greatly from knowing more about the experiences of other state programs. Similarly, many industrial companies have internal risk assessment processes that develop numerical values and are willing to share their experiences. In addition, many customers expressed interest and concern about the global role of IRIS.

Analytical Approach Used For Suggesting Pilot Projects

The following suggestions have been developed by ENVIRON, based on information collected from frequent IRIS users, and on knowledge of the current state of the IRIS program and process. The customers interviewed expressed interest in several initiatives and communication mechanisms; ENVIRON used the information to develop specific suggestions that are presented below.

Pilot Project Suggestion #1: Establish a IRIS Dialogue Group

All the frequent customers interviewed expressed interest – in varying degrees- in participating in an IRIS dialogue group. Many of the customers have participated in other federal agency-sponsored dialogue and advisory groups and believe that a similar group for the discussion of IRIS is warranted. The group could provide advice to EPA, but the most important need is a forum for two-way communication, therefore the emphasis should be on exchanging information and views rather providing advice.

A dialogue group could be established in a couple of ways, therefore it is best to consider different approaches, but all having the same goals in mind. There are two basic goals:

- Have frequent IRIS customers provide information, based on use experience, to the Agency so it can fully consider their needs and views when making IRIS related decisions;
- Make customers more informed about the IRIS process so that they can better understand and appreciate the challenges of issuing peer reviewed, Agency

consensus files. The more informed the customers are, the better able they are to offer useful information and insights.

Two key considerations are membership and legal status. The membership issue is whether to have a broad-based group comprised of representatives from various customer categories or to have separate groups of similar users. The legal issue is whether to make the group a formal ORD body, using a mechanism already in place, such as the Board on Scientific Counselors (BOSC); or relying on a contractor to assemble a group in which ORD would participate.

Another key consideration is timing. Many frequent customers, particularly state regulatory agency users, feel a strong sense of urgency regarding IRIS. They know they must soon make decisions on a large number of "controversial" chemicals for which there are no IRIS files.

Option #1A: Broad Based Formal Group

This group would include representatives from each of the nine customer categories presented in the Findings Report, but with greater representation from state agencies and regulated parties, because of their greater dependence on IRIS. The group would be a "formal" ORD body, most likely a sub-committee of the BOSC. The group members would be frequent IRIS users, thus they would likely be scientists, not necessarily senior officials within their organization. However, there could be an emphasis placed on finding senior managers who are also frequent IRIS users.

The agendas for the meetings would reflect the membership and thus be rather broad, addressing a range of issues appealing to customers who use IRIS as a source of comprehensive information on a chemical; and those who are dependent on IRIS for making regulatory-related decisions.

The benefits of such a body are that it would be acknowledged as the principal IRIS customer group and its input would be documented and fully considered. A negative is that it will likely take longer to establish a "formal" body than it would an informal group. Another concern is that its wide ranging membership will cause the meeting agendas and discussion to be unwieldy and difficult to schedule. Similarly, the diverse membership could also result in a level of intransigence or at least a reluctance to be fully forthcoming with views and experiences.

Option #1B: State Agency Customer Group

This group would consist mostly of representatives from state environmental regulatory agencies but include a smaller number of public health agency officials. The group would require travel funds provided by ORD or its contractor. The membership would not necessarily include all 50 states; rather it would be more effective to have a smaller group, with representatives from states with different needs and expectations.

It is recommended that the group not be a formal ORD body; rather it's "membership" should be flexible, although restricted to state officials who are IRIS users. However, there would need to be a core of members wiling to work with ORD or its contractor, to assist in developing agendas, facilitating discussions, and providing leadership. One approach would be for ORD or its contractor to hold 2-4 workshops, likely in different regions of the country, featuring a mix of presentations and discussions regarding IRIS experiences and needs. The workshops would be scheduled and developed with input from a core group of state officials but participation would be open to all state officials. However, given the shortage of state travel funds, it is likely that only those receiving financial assistance would be able to attend.

The benefit of such a group is that its agenda would be focused and would allow ORD to address the concerns of key customers who have immediate and long term needs. In addition, the dialogue would contribute to the larger issue of state-EPA relations. IRIS is highly valued by states, it is likely one of the most visible and impactful products the Agency provides to states.

Currently there is no direct mechanism for state customers to interact directly with ORD on IRIS and other risk assessment-related issues. State officials do routinely interact with EPA, but typically through Region or program offices. In addition, the Environmental Council of the States (ECOS) has established the Interstate Technology and Regulatory Council (ITRC) which includes a Risk Assessment Resources Team. Although IRIS is discussed at these forums, it is not at the forefront and most importantly ORD is typically not represented.

Option #1C: Industry Customer Group

This group would consist of companies, from different industry sectors – chemical manufacturing and use, food, pharmaceuticals, aerospace, automobiles -- who are impacted by IRIS. The charge to the group would be to characterize the impact IRIS has on operations domestically and globally and to document how IRIS could better address their needs.

This effort would not have to rely on EPA funding, but would require a commitment from ORD to participate in the industry sessions and to fully consider the findings presented. The group would be organized by a contractor who would seek funding from members.

The industry group would focus on the broader issue of the role and importance of IRIS in the decision-making process; including decisions made via the marketplace and by EPA, states, other countries, regional and global organizations. The industry group would consist of senior company officials, not necessarily risk-assessors, who could take a higher level viewpoint regarding the role of IRIS. The group would meet periodically in the first three quarters of 2008 and would issue a findings statement in the last quarter of the year.

One benefit of this approach is that ORD would receive useful input without having to expend funds that could be spent on related efforts, such as a state IRIS user group. Furthermore, the group would be motivated to make effective use of the time and resources allocated; thereby ensuring that position papers and other material are issued in a prompt manner.

Conclusions

Three alternatives for an IRIS customer dialogue group have been presented; each has merit and would contribute greatly to improved relations and information flow. However, the approaches can be mixed and matched. For example, an "informal" broad based dialogue group could be established; or a "formal" industry customer group could be established as a BOSC sub-committee. But a dialogue group of some sort should be established quickly, perhaps with the understanding that it is a pilot effort, which will likely evolve, with changes in legal status, membership, and expectations.

Pilot Project Suggestion #2: Conduct Further Analysis

The project Findings Report is a useful document that provides a solid overview of the experiences and views of a small but highly significant, sampling of IRIS customers. However, the Report only provides a cursory assessment of a number of key issues that warrant further consideration. It would be useful to conduct a more detailed analysis focused on the priority issues identified in the Findings Report. Three pilot projects should be considered.

Option #2A: State Risk Assessment Process: Use of an IRIS File Compared to the Absence of an IRIS File

The analysis would focus on how states use IRIS in the decision-making process and how the absence of an IRIS file impacts the process. A case study approach would be used, examining the process used by approximately five states. A contractor would collect information from state guidance documents and other publicly available information, and meet with state risk assessors and decision makers to document the process used and the challenges faced.

States with differing capabilities would be analyzed. There would be two case studies for each state examination; one example would involve the use of an IRIS file in developing the science component of a regulatory decision. The second example would examine how the process changes when there is no IRIS file, and document the additional resources and time allocated due to its absence.

The analysis would result in a more concrete demonstration of the impact of IRIS on the state decision making process.

Option #2B: Industry Risk Assessment Process: Use of IRIS

This analysis would be similar to the state examination except that the industrial companies are regulated parties. Information collected during the project indicates that many companies go through a risk assessment and numerical value-setting process similar to the IRIS file development experience. They use the results of their own analysis to provide a "check" against an IRIS file or a numerical value developed by another regulatory authority.

The recommended analysis would describe the risk assessment process used by one or more companies, focusing on the role of IRIS in the process. Of particular interest would be the knowledge of when and how IRIS is precisely used. In addition, the analysis would describe what occurs in the absence of an IRIS file.

The benefit of this type of analysis is in capturing industry risk assessment practices and documenting the importance of IRIS in that process. Chemical companies typically believe that risk assessment is a necessary element of product stewardship. Companies want government, the science community, and the general public to understand that they assess the risk of products throughout the product development and life cycle. However, companies have been understandably cautious about describing in detail their risk assessment practices. However, selected companies are willing to describe how they use IRIS, and other information sources, in conducting scientific assessments.

Option #2C: Facilitating Use of IRIS Globally

A concern expressed by some industrial companies is that the European Union and other regional and global organizations are increasingly involved in risk assessment-related activities -- which could have global implications – and are doing so without the benefit of a strong U.S. voice. Although regulated parties may challenge some IRIS values, they generally believe that IRIS, with a transparent review and comment opportunity, should be viewed as a global example.

An analysis would document the experiences of U.S. based industrial companies in using IRIS and other toxicological databases overseas. The analysis would address the issue of whether and how the consistent use of IRIS globally will impact the companies.