

**Missouri Department of Natural Resources
Regulatory Impact Report
In Preparation For Proposing
An Amendment of Health Profile Rule, 10 CSR 25-7.264(2)(P)**

Division/Program: Division of Environmental Quality Hazardous Waste Program

Rule number: 10 CSR 25-7.264

Rule Title: Standards for Owners and Operators of Hazardous Waste Management Facilities

Type of rule action: Amendment

Nature of the rulemaking: Affects environmental conditions and prescribes environmental standards for details of Health Profiles, required by 260.395.7(5) RSMo to be submitted with applications for hazardous waste operating disposal or treatment facility permits

Approval of the Completed Regulatory Impact Report

Program Director

Date

Missouri Department of Natural Resources
Regulatory Impact Report
In Preparation For Proposing
An Amendment of Health Profile Rule, 10 CSR 25-7.264(2)(P)

Applicability: Pursuant to Section 640.015 RSMo, “all rulemakings that prescribe environmental conditions or standards promulgated by the Department of Natural Resources...shall... be based on the regulatory impact report...” This requirement shall not apply to emergency rulemakings pursuant to section 536.025 or to rules of other applicable federal agencies adopted by the Department “without variance.”

Determination: The Missouri Department of Natural Resources has determined this rulemaking prescribes environmental conditions or standards and verifies that this rulemaking is not a simple unvarying adoption of rules from other federal agencies. Accordingly, the Department has produced this regulatory impact report which will be made publicly available for comment for a period of at least 60 days. Upon completion of the comment period, official responses will be developed and made available on the agency web page prior to filing the proposed rulemaking with the Secretary of State. Contact information is at the end of this regulatory impact report.

1. Describe the environmental conditions or standards being prescribed.

Health profiles are required by the Revised Statutes of Missouri Section 260.395.7(5) for certain types of facilities as part of the hazardous waste permitting process administered by the Missouri Department of Natural Resources (DNR). The purpose of the profile is to identify the hazardous waste that a permitted treatment or operating disposal facility will routinely handle and to examine the potential for human health effects that could result from exposure to the hazardous waste resulting from these permitted activities. Once identified, the regulations require that any change in indicators of those health effects in the immediate area of the facility be compared to the same indicators within other geographical areas in order to identify any trends that may exist over a specific period of time. By examining these trends, the state can determine whether a facility may be causing an increase in these indicators.

2. A report on the peer-reviewed scientific data used to commence the rulemaking process.

As part of the stakeholder process, participants were invited to provide comments on the current process and suggestions for changes and improvements to the process. Listed below are three documents brought to the department’s attention during the stakeholder process. These documents were cited as a basis for some of the comments provided by stakeholders on the health profile process. The department neither agrees nor disagrees with the contents or conclusions of any of these documents.

- a. Friedman G.D.: Primer of Epidemiology Third Edition, McGraw-Hill, New York, 1987

- b. Morgenstern, H.: Uses of Ecologic Analysis in Epidemiologic Research. AJPH 72(12), 1982, pp. 1336-1344
- c. Lilienfeld A.M. and Lilienfeld D.E.: Foundations of Epidemiology, Second Edition, Oxford University Press, New York, 1980

3. A description of the persons who will most likely be affected by the proposed rule, including persons that will bear the costs of the proposed rule and persons that will benefit from the proposed rule.

All hazardous waste treatment and operating disposal facilities are required to submit health profiles with their permit applications. There are currently twelve facilities in Missouri that require health profiles. The Department of Natural Resources shares the submitted health profiles with the Department of Health and Senior Services (DHSS). The health agency reviews and evaluates the profiles and provides information back to the DNR.

Incinerators

- BASF Corporation, Palmyra
- Bayer Cropscience, Kansas City
- Lake City Army Ammunition Plant, Independence
- EBV Explosives Environmental Company, Carthage

Cement Kilns

- Lone Star Industries, Cape Girardeau
- Continental Cement Company, Hannibal
- Holcim Inc./Geocycle LLC, Clarksville (kiln closed and plant is currently idle but may operate as a miscellaneous treatment facility in the future)

Hazardous Waste Landfill

- Exide Technologies, Forest City
- Buick Resource Recycling Facility, Boss

Miscellaneous Treatment Facilities

- Solvent Recovery Corporation, Kansas City
- Heritage Environmental Services, LLC, Kansas City
- Waste Express, Kansas City

4. A description of the environmental and economic costs and benefits of the proposed rule.

The department anticipates that amending the regulations that implement the statutory requirement for hazardous waste treatment and operating disposal permitted facilities to submit health profiles will provide the public, the state, and the facility with more meaningful data on health effects potentially attributable to potential releases from the facility. Currently, the data submitted as part of the health profiles submitted by facilities is expensive to compile, time-consuming to review, and for various reasons not as meaningful as it could be. Additionally, there are other duplicative and overlapping requirements now in the regulations that work together to assess the potential for release and associated health impacts that could be attributed to the facility operations.

The current regulation requires the facility to identify three geographic regions, one region that includes the facility, another region to provide a local comparison, and a final region that includes a statewide comparison group. The population residing within a three to five mile radius of the facility comprises the first region and has the highest potential exposure to releases from the treatment or operating disposal unit(s), the population within the second region has less potential exposure, and the final region has insignificant potential exposure to any releases from the units and is considered a control group for the other regions.

Among these geographic regions, the health profile compares mortality data, hospital discharge data, cancer incidence data, natality data, birth defect data, and fetal death data for the five most recent years the data was available from the DHSS against the health effects identified or those that might be associated with releases from the treatment or operating disposal unit(s). In addition, the facility must request mortality and hospital discharge information on eight major categories of cancer from the mortality and hospital discharge database. All of this information is compiled and submitted as part of the facility's health profile. The profile is submitted to the DNR, which then shares the profile with the DHSS.

For more than twenty years the existing regulation has been in effect, the Bureau of Epidemiology and the Bureau of Health Informatics and their predecessors within the DHSS have provided data and technical assistance to facilities developing health profiles. DHSS has reviewed the health profile documents and made recommendations to the DNR on the adequacy of the documents. In reviewing these documents over the years, DNR and DHSS staff have identified several issues with respect to the way health profiles are prepared that lead DNR and DHSS to believe that the health profiles submitted by the facilities in accordance with the current regulations may not present a meaningful picture of potential health impacts associated with potential exposures to releases from the treatment or operating disposal unit(s).

The proposed rule is intended to address the knowledge gained in the health profile preparation process as identified by regulated facilities and staff from DNR and DHSS, and to improve the process based on that knowledge. Major flaws recognized over time that necessitate the rule improvement are described herein. In rural areas, where many of the permitted facilities are located, hospital discharge data is not necessarily a reliable indicator of the health of local residents. There may be no hospitals within the zip code search area addressed by the health profile, thus any health effects on local residents would not be represented in hospital discharge

data because those residents would be discharged from hospitals outside the search area. Hospital discharge data are also not reliable indicators of chronic diseases such as cancer because many chronic diseases require multiple hospital visits. As such, multiple hospital visits/discharges may result in the over-representation of a single type of disease or illness.

Another factor impacting the validity of the data contained in the health profile is the overall age of residents in the study area. Age is one of the most important factors in assessing the rate of occurrence of diseases. Because the age of rural residents tends to be higher than comparable non-rural areas, a study that focuses solely on a rural area will likely find a higher rate of occurrence of chronic diseases that typically occur with increasing frequency with age. The health indicators data submitted with a health profile does not differentiate the occurrence of disease attributed to age and that attributable to other factors.

Because most facilities are located in rural areas, there are statistical issues with data gathered from the affected geographic regions. Rural areas have a limited population from which to obtain data on various health effects and few, if any, local hospitals from which to obtain hospital discharge data. Further, local residents in rural areas often drive elsewhere to access health services, so data on any health effects for those residents would not be captured by the current data collection process. The current health profile methodology gathers data in a defined geographic area by zip code. Through use over 20+ years, staff have found that zip code-based data do not accurately or adequately represent the population potentially affected by release from the treatment or operating disposal unit(s). In sparsely populated areas, zip code areas are often far too large and most of the population within that zip code may actually live in an area least likely to receive any releases from the treatment or operating disposal unit(s). The small sample size that results from obtaining data from a sparsely populated area also makes it difficult to draw valid statistical conclusions about rates of disease/illness.

The existing health profile process does not take into account population migration. Many of the effects of exposure to releases have been shown to take a long time to develop. People living in an area during the study period may not have lived there long enough to be have been potentially affected by releases from the treatment or operating disposal unit(s). Those who have been potentially affected may have moved out of the study area so any health conditions associated with those individuals would not be represented in the data. For all the above reasons, the data currently compiled by facilities as part of the health profile process may not accurately, or even approximately, represent the health effects associated with exposure to releases from the treatment or operating disposal unit(s), and also the data does not first acknowledge whether there is the potential for release from the facility based on the type of unit/operations and environmental/safety controls in place through the permit.

The benefit of revising the existing regulations is that data collected under the proposed changes to the regulations will be better optimized by providing more meaningful insights into the potential for releases from the treatment or operating disposal unit(s) and also into the actual and potential health impacts associated with those releases, while also costing less to compile and avoiding duplication by the facilities and MDNR. Collection of more meaningful data will, in turn, provide a firmer basis of support for implementation of any necessary release control measures at such facilities.

The proposed changes incorporate existing requirements that address many of the same issues associated with controls for releases, and the potential for related health impacts from treatment or operating disposal units that manage hazardous waste. By using information submitted by facilities that have these units, the potential for duplication is limited and the process is more efficient and less costly while still gathering relevant information on the potential for releases and related health impacts of releases from units that manage treat or dispose of hazardous waste. The proposed changes also provide additional options and flexibility for facilities that are required by statute to submit health profiles that are optimized based on the nature of the unit/facility. The ability to use information already required by other components of the regulations for hazardous waste treatment and operating landfill units is expected to enhance the level of support for health-based decision-making when compared with the current process.

5. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenue.

Currently, the DNR receives the health profiles along with permit applications, or permit renewals. The DNR passes the health profile on to the DHSS for their review. Both departments agree that the current process is time-consuming and costly and does not accurately represent hazardous waste treatment or disposal unit(s) potential for releases, or related potential impacts on public health. Each department believes that amending the regulations will reduce the amount of time required to provide a thorough review of the data submitted with the health profile, which will allow permits to be issued more quickly, saving money for both the agencies and the permittee.

6. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction, which includes both economic and environmental costs and benefits.

If the existing regulations are not amended, facilities will continue to submit health profiles in the same format as currently required. As discussed previously, the current format and data requirements present challenges that the department hopes to address with the proposed changes. One cost of inaction is that facilities will continue to incur the substantial expense of gathering the required data despite the limitations on use of the data described above. Facilities will also continue to be billed by the DNR and the DHSS for the staff time to review the health profile. We expect the cost of preparing the health profile and the cost to review the health profile will be higher under the current process than under the process that would be established by the proposed changes. Modification of the current process will save facilities money, will decrease DNR/DHSS staff review time, will decrease permit issuance time frames, and will optimize the rule based on the type of unit and site-specific characteristics. If the current system is left in place, the data gathered by the facilities will continue to have the same issues and limitations discussed previously in this report. By proceeding with the proposed rule, we expect to make the process more efficient and less costly while increasing the value of health profiles in gauging the actual potential for releases and potential health effects related to potential releases from treatment or operating disposal unit(s) and thereby providing the basis for consideration and implementation of enhanced release controls, as appropriate, at permitted treatment or operating

disposal unit(s). Our objective in this rulemaking is to continue to satisfy the statutory requirements for health profiles by keeping elements of the current process that work and replacing process elements that do not provide useful/meaningful information.

7. A determination of whether there are less costly or less intrusive methods for achieving the proposed rule.

The statute requires health profiles and establishes minimum standards to be addressed by the profile. DNR/DHSS believe that the proposed rules will provide for a less-costly, more focused and more meaningful alternative to the current process while still meeting the statutory requirements. In some respects, the proposed rules are expected to provide for a health profile process that is somewhat less “intrusive” than the current process. The rule has been written to be optimized based on the potential for release, and based as much as possible on using the same information used to meet other requirements.

8. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the department and the reasons why they were rejected in favor of the proposed rule.

The DNR formed a workgroup to assess the need for changes to the health profile regulations. That workgroup met at Hazardous Waste Forums held on May 10, 2007, October 23, 2007, and April 8, 2009. Workgroup members considered a range of options for addressing the problems with health profiles discussed in the workgroup. The options considered ranged from no action at all to modifying the regulations, issuing variances, changing the law, using a risk assessment or health assessment document in lieu of the health profile, or creating registries by going door to door to gather information on the health of local residents. All of the options considered by the workgroup were listed in a document prepared by department staff titled “Matrix of Potential Health Profile Options” dated May 22, 2008. The matrix presented pros and cons for each of the various options. The workgroup considered each of the options, but for various reasons which were discussed at the forums and summarized in the meeting notes, the group reached a consensus that the health profile regulations could be improved and that DNR would initiate the rulemaking process to do so. Specifically, the group determined that the rules could be amended so that the outcome of the health profile process would be more accurate and contain meaningful data that will assist DNR/DHSS in determining the potential for and character of potential health impacts that may be attributable to permitted treatment or operating disposal unit(s) and whether additional facility release controls appear warranted to mitigate any such potential impacts.

9. An analysis of both short-term and long-term consequences of the proposed rule.

In the short term, facilities and DNR/DHSS will face a learning curve as they become familiar with the new requirements. This may initially result in some minor delays in health profile preparation as DNR/DHSS and facilities work together to determine what information facilities are required to submit and when they are required to submit it. As DNR/DHSS and facilities work through the issues associated with implementation of the new process, the review of health profiles may take a bit longer. Once facilities and state agency staff become familiar with the

new process, we expect that health profiles will be more focused, efficient, timely and less costly. In the short term, DNR will work with facilities that are in the process of applying for permit renewals to determine which requirements will apply to their permit applications. Once the amended regulations are in effect, this will not be a long-term issue.

10. An explanation of the risks to human health, public welfare or the environment addressed by the proposed rule.

The current regulation requires certain permitted facilities to compile detailed information on potential human health effects within the geographic area where the facility is located and compare that data to data for the same categories of potential human health effects from nearby and state-wide geographic areas. The objective of this comparison is to identify first whether there may be the potential for elevated rates of disease/illness in areas proximate to a facility and, if so, to provide the basis for the implementation of additional release controls in the facility's permit. The proposed rule establishes a revised process to evaluate the potential for human health effects related to potential releases associated with treatment and/or operating disposal activities at permitted hazardous waste facilities.

The proposed rule revisions establish a process by which hazardous waste treatment and/or operating disposal facilities can satisfy the requirement to complete a health profile with their original hazardous waste permit application and with any subsequent applications for permit modifications or renewals that include a significant change. In each case, facilities would have various options to satisfy this requirement. Those available options depend on the nature of the unit/facility operations and can include either a risk assessment focused on the potential for exposure pathways or a health assessment by the DHSS requested by the facility through the DNR that is optimized by being site-specific. Both of these subsequent approaches would evaluate the type and concentration of contaminants/chemicals managed in the treatment and/or operating disposal unit(s), the potential for release, and potential routes of human exposure, if applicable, to such contaminants/chemicals in making this determination.

11. The identification of the sources of scientific information used in evaluating the risk and a summary of such information

Guidelines for Hazardous Waste Health Profile, July 2005, Missouri Department of Health and Senior Services

12. A description and impact statement of any uncertainties and assumptions made in conducting the analysis on the resulting risk estimate.

The proposed rule revises the requirements for completing health profiles. The proposed revisions will provide for incorporation and consideration of requirements that address the potential for release and relevant risk- and health-based analyses/evaluations that address issues similar to those that are addressed under the current health profile process. The existing analyses/evaluations will include evaluating prevention methods, and monitoring of actual releases, the potential for human exposure to such releases, if applicable, and the possible health effects that may result. As an example, since the effective date of the health profile rules, the

Environmental Protection Agency has promulgated rules for combustion facilities that address essentially the same overall needs. The federal requirements are found in 40 CFR 270.10(l). The hazardous waste combustion regulations were proposed and adopted based on detailed risk assessments conducted by the Environmental Protection Agency as part of the rule development process. To the extent that the proposed changes to the health profile regulations incorporate those federal regulations, the same assumptions identified in the federal regulations will apply. Specifically, the federal rule which established emissions standards for combustors that burn hazardous waste is titled “National Emission Standards for Hazardous Air Pollutants: Final Standards for Air Pollutants for Hazardous Waste Combustors” and was adopted on October 12, 2005. Supporting documentation for the rule is part of the rulemaking docket and is available on EPA’s website. As for combustors, the RCRA regulations as administered by EPA and MDNR allow the evaluation of potential for release based on the type of treatment/land disposal, and the evaluation of pertinent potential health impacts.

13. A description of any significant countervailing risks that may be caused by the proposed rule

The proposed rule eliminates the need to submit a health profile in some situations. After a facility submits its original permit application, a health profile will only be required in specific circumstances. Currently, health profiles must be submitted with the original permit application, and with any each request for permit renewal. By eliminating the requirement to submit a health profile with a permit renewal when there are no significant changes, it is possible that it will be more difficult to identify a health-related trend or impact. However, the proposed changes include requirements that should minimize the potential for this to occur, thus the rule being “optimized”. For example, if any changes to the facility occur that may increase the potential for human exposure, the facility must submit an updated health profile as part of the application for that change. Additionally, the DHSS has the authority to require additional investigation if the information reveals potentially unacceptable health risks. Together, these requirements should minimize the possibility that possible health impacts or trends are overlooked for facilities during ongoing operations and when changing their process through subsequent permit changes/renewals.

14. The identification of at least one, if any, alternative regulatory approaches that will produce comparable human health, public welfare or environmental outcomes.

Because health profiles are a statutory requirement, rescinding the existing regulation is not an option. One alternative regulatory approach would be to continue using the current health profile process despite its limitations. The current regulations do not produce information that can be used in a meaningful way to assess the potential impact that hazardous waste treatment and/or operating unit(s) have on public health. For the reasons discussed in responses to other questions in this Regulatory Impact Report, the current process is inherently flawed because of the underlying problems associated with the assessment areas, population migration and the statistical limitations of the data. The department believes that the regulations can be revised to provide more accurate and optimized information; streamline the health profile process to make it more timely, efficient and cost effective; eliminate duplication of overlapping regulatory requirements; provide additional flexibility in complying with the statutory requirements and provide a better foundation for departmental decisions regarding the need (or lack thereof) for

additional facility release controls in hazardous waste treatment and/or operating disposal permits.

15. Provide information on how to provide comments on the Regulatory Impact Report during the 60-day period before the proposed rule is filed with the Secretary of State

Comments may be submitted by electronic mail to Tim Eiken, Rule Coordinator of the Hazardous Waste Program at tim.eiken@dnr.mo.gov, or submitted by mail to:

Tim Eiken, Rule Coordinator
Missouri Department of Natural Resources
Hazardous Waste Program
P.O. Box 176
Jefferson City, MO 65102-0176

In your email or letter, please mention that the comments are on the Regulatory Impact Report for the Health Profile Rulemaking. It is also helpful if the comments are directed to specific portions of the report.

16. Provide information on how to request a copy of comments or the web information where the comments will be located.

Information related to this proposed rulemaking and regulatory impact report, including comments on the RIR, will be posted on the web at:

<http://www.dnr.mo.gov/env/hwp/hprofile/profilewkgrp.htm>

This site will be updated and expanded as the rulemaking effort progresses. If you would like to receive information and updates from the department on the status of this rulemaking, please contact Lynn Hartman at the department's Hazardous Waste Program at 800-361-4827 or 573-522-1834 or by email at lynn.hartman@dnr.mo.gov. If you have any questions about health profiles, please contact Darleen Groner at the department's Hazardous Waste Program at 800-361-4827 or 573-751-3553 or by email at darleen.groner@dnr.mo.gov