

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

BUREAU OF AIR

DIVISION of AIR POLLUTION CONTROL

PERMIT SECTION

Springfield, Illinois

PROJECT SUMMARY for the
DRAFT CLEAN AIR ACT PERMIT PROGRAM (CAAPP) PERMIT

Solutia, Inc.
W.G. Krummrich Plant
500 Monsanto Avenue
Sauget, Illinois 62206-1198

Illinois EPA ID Number: 163121AAC

Application Number: 96010001

Application Type: Initial Permit

Start of Public Comment Period: November 15, 2007

Close of Public Comment Period: December 15, 2007

Permit Engineer/Technical Contact: Dan Punzak, 217/782-2113

Community Relations/Comments Contact: Brad Frost, 217/782-7027

I. INTRODUCTION

This source has applied for an initial Clean Air Act Permit Program (CAAPP) operating permit. The CAAPP is the program established in Illinois for operating permits for significant stationary sources as required by Title V of the federal Clean Air Act and Section 39.5 of Illinois' Environmental Protection Act. The conditions in a CAAPP permit are enforceable by the Illinois Environmental Protection Agency (Illinois EPA), the USEPA, and the public. This document is for informational purposes only and does not shield the Permittee from enforcement actions or its responsibility to comply with applicable regulations. This document shall not constitute a defense to a violation of the Act or any rule or regulation.

A CAAPP permit contains conditions identifying the applicable state and federal air pollution control requirements that apply to a source. The permit also establishes emission limits, appropriate compliance procedures, and specific operational flexibility. The appropriate compliance procedures may include monitoring, record keeping, and reporting to show compliance with these requirements. The Permittee must carry out these procedures on an on-going basis to demonstrate that the source is operating in accordance with the requirements of the permit. Further explanations of the specific provisions of the draft CAAPP permit are contained in the attachments to this document, which also identify the various emission units at the source.

A draft of this permit previously went to public notice in 2004 but a permit was never issued. Since then many of the processes/operations at the site have been shut down and thus this permit is much shorter than the previous version. However, there are some major regulations [National Emissions Standards for Hazardous Air Pollutants (NESHAP), specifically for Miscellaneous Organic Chemical Manufacturing] that will take effect shortly after this permit is expected to be issued so those regulations will be cited in the permit although the source will not have to comply until the final compliance date for the regulation, May 10, 2008.

II. GENERAL SOURCE DESCRIPTION

a. Nature of source

The Krummrich plant produces various types of chemical intermediates and final products. Solutia is considered to be the operator and the equipment for each of the three main chemicals produced is owned by a different company.

b. Ambient air quality status for the area

The source is located in an area that is currently designated nonattainment for the National Ambient Air

Quality Standards for ozone (moderate nonattainment) and/or PM_{2.5} and attainment or unclassifiable for all other criteria pollutants (NOx, SO₂, CO and lead).

c. Major source status

1. The source requires a CAAPP permit as a major source of hazardous air pollutant (HAP) emissions.
2. The source also requires a CAAPP permit because the source is considered a single source with Environmental Management Corp., I.D. No. 163121AAY, located at 2301 Falling Springs Road, Sauget, IL. The Permittees have elected to obtain separate CAAPP permits for their operations.

d. Source Emissions

The following table lists annual emissions of criteria pollutants from this source, as reported in the Annual Emission Reports sent to the Illinois EPA.

Pollutant	Annual Emissions (tons)				
	2006	2005	2004	2003	2002
CO	1.5	1.66	1.59	0.43	0.05
NOx	1.8	2.0	3.7	17.1	21.8
PM	6.6	6.1	7.6	13.7	14.27
SO ₂	1.1	0.7	0.79	0.02	0.02
VOM	39.2	50.1	61.9	95.4	109.7
(top HAP)	1.8(CL)	2.04(CL)	6.7(DCB)	25.6(MIBK)	34.1(MIBK)

III. NEW SOURCE REVIEW / TITLE I CONDITIONS

This draft permit contains terms and conditions that address the applicability of permit programs for new and modified sources under Title I of the Clean Air Act (CAA) and regulations promulgated thereunder, including 40 CFR 52.21, Prevention of Significant Deterioration (PSD) and 35 IAC Part 203, Major Stationary Sources Construction and Modification. Any such terms and conditions are identified within the draft permit by T1, T1R, or T1N. Any conditions established in a construction permit pursuant to Title I and not revised or deleted in this draft permit, remain in effect pursuant to Title I provisions until such time that the Illinois EPA revises or deletes them. Where the source has requested that the Illinois EPA establish new conditions or revise such conditions in a Title I permit, those conditions are consistent with the information provided in the CAAPP application and will remain in effect pursuant to Title I provisions until such time that the Illinois EPA revises or deletes them.

This draft permit would establish new Title I requirements.

IV. COMPLIANCE INFORMATION

The source has certified compliance with all applicable rules and regulations; therefore, a compliance schedule is not required for this source. In addition, the draft permit requires the source to certify its compliance status on an annual basis.

V. PROPOSED ILLINOIS EPA ACTION / REQUEST FOR COMMENTS

It is the Illinois EPA's preliminary determination that this source's permit application meets the standards for issuance of a CAAPP permit. The Illinois EPA is therefore proposing to issue a CAAPP permit, subject to the conditions proposed in the draft permit.

Comments are requested by the Illinois EPA for the draft or proposed permit, pursuant to 35 IAC Part 252 and Sections 39.5(8) and (9) of the Illinois Environmental Protection Act. A final decision on the draft or proposed permit will not be made until the public, affected states, and USEPA have had an opportunity to comment. The Illinois EPA is not required to accept recommendations that are not based on applicable requirements. If substantial public interest is shown in this matter, the Illinois EPA will consider holding a public hearing in accordance with 35 IAC Part 166.

ATTACHMENT 1: Summary of Source-Wide Requirements

The following table indicates the source-wide emissions control programs and planning requirements that are applicable to this source. These programs are addressed in Sections 5 and 6 of the draft permit.

Program/Plan	Applicable
Emissions Reduction Market System (ERMS)	No
Nitrogen Oxides (NO _x) Trading Program	No
Acid Rain Program	No
Compliance Assurance Monitoring (CAM) Plan	No
Fugitive Particulate Matter (PM) Operating Program ^a	Yes
Risk Management Plan (RMP) ^b	Yes
PM ₁₀ Contingency Measure Plan	No

- a. The fugitive PM operating program is required to significantly reduce fugitive particulate matter emissions from certain affected locations and facilities (35 IAC Part 212.309 - 212.312). Normally, elements of this program include, but are not limited to, addressing normal traffic pattern roads, parking facilities, and material piles and handling through the use of water, oils, or chemical dust suppressants.

- b. The RMP is a program for reducing the levels of emissions during an emergency, consistent with safe operating procedures (Section 112(r) of the federal Clean Air Act). The program requires the immediate implementation the appropriate steps described in this plan should an emergency be declared. The Permittee is required to maintain and have this plan on file with the USEPA

ATTACHMENT 2: Summary of Requirements for Specific Emission Units

The following tables include information on the requirements that apply to significant emission units at this source. The requirements are found in Section 7 of the draft permit, which is further divided into subsection, i.e., Section 7.1, 7.2, etc., for the different categories of units at the source. A separate table is provided for each subsection in Section 7 of the draft permit. An explanation of acronyms and abbreviations is contained in Section 2 of the draft permit.

Table 1 (Section 7.1 of the draft permit)

Emission Unit - Santoflex Process	
Description	The Santoflex department consists of two similar lines referred to as Line 1 and Line 2. Both lines are batch operations involving three main steps: reaction, filtration, and distillation. All of the products manufactured in these lines are rubber antidegradants.
Date Constructed	Primarily 1986
Emission Control Equipment	Condensers, Scrubbers and Separators
Applicable Rules and Requirements	
Emission Standards	35 IAC 219 Subpart V, Batch Operations. 35 IAC 219 Subpart G. 35 IAC 212.321. 40 CFR 63 Subpart FFFF (the MON, effective in May 2008).
Streamlining	N/A
Title I Conditions	The draft permit contains limits on operation and emissions in Conditions 7.1.5 and 7.1.6. These limits were incorporated from Permits 84090063 and 00110001.
Non-applicability	40 CFR 60 Subpart RRR: The reason for non-applicability is explained in detail in the permit. 40 CFR Part 63, Subparts F through H: The reason for non-applicability is explained in detail in the permit. 35 IAC 219 Subpart Q: The reason for non-applicability is explained in detail in the permit. 35 IAC 219 Subpart RR: The reason for non-applicability is explained in detail in the permit. 40 CFR Part 64, Compliance Assurance Monitoring (CAM): The reason for non-applicability is explained in detail in the permit.
Periodic Monitoring (other than basic regulatory requirements)	

Emission Unit - Santoflex Process	
Testing	Performance test required by 40 CFR 63 when it becomes effective in May 2008. Upon request tests must be performed to demonstrate compliance with 35 IAC 219 Subpart V but complying with the more stringent standard (98% verses 90%) of 40 CFR 63 should be sufficient unless the test methods are not similar enough.
Emissions Monitoring	None of the monitors directly measure emissions. Parameter monitoring of the control equipment is the general method of monitoring. See below.
Operational Monitoring	40 CFR 63 Subpart FFFF does not include specific items to be monitored but does say that whatever variables are necessary to demonstrate compliance during the performance test must be monitored at all times and a range for those monitored variables be established. The general requirements of Subpart A also apply. The 35 IAC 219 Subpart V rules include specifications for use of scrubbers and condensers as control equipment. 40 CFR 63 Subpart FFFF requires leak monitoring of components but then specifies that the procedures in Subpart TT or UU should be followed. The hopper must be observed for visible emissions once per week. This source is a low emitter of PM and once per week is sufficient.
Inspections	N/A
Recordkeeping	40 CFR 63 Subparts FFFF and A specify detailed recordkeeping to comply with the NESHAP. 35 IAC 219 Subpart V specifies detailed recordkeeping requirements including those for units that are small enough not to require control. Weekly visible emission observations. Emission records to verify compliance with the T1 limits in Condition 7.1.6
Other	It should be noted that the source has granted a construction permit for equipment to comply with the future NESHAP requirements (40 CFR 63 Subpart FFFF). If the equipment is constructed by the time the final permit is ready to be issued, that new equipment will be included. The construction permit is not new emission units but only control equipment to reduce emissions.
Reporting	
Prompt Reporting	Noncompliance with the rules in Condition 7.1.3, with the control requirements in Condition 7.1.5 or with the limits in Condition 7.1.6
Other Reporting	40 CFR 63 Subparts FFFF or A. Notifications of the above rule such as upcoming performance tests.
Other Information	

Emission Unit - Santoflex Process	
Footnotes	
Other	Note that in quoting some applicable state rules for recordkeeping the rule may state that records need to be kept for a minimum of three years. This does not relax the general CAAPP requirement that records be kept for five years.

Table 2 (Section 7.2 of the draft permit)

Emission Unit - Santoflex Process Storage Tanks	
Description	Storage tanks used in the production of Santoflex.
Date Constructed	1977
Emission Control Equipment	Each tanks has its own condenser.
Applicable Rules and Requirements	
Emission Standards	35 IAC 219.120. 35 IAC 219.301. 40 CFR 63 Subpart FFFF (the MON, effective in May 2008).
Streamlining	
Title I Conditions	The draft permit contains limits on operation and emissions in Conditions 7.1.5 and 7.1.6. These limits were incorporated from Permit 84090063.
Non-applicability	40 CFR 60 Subpart Ka: The reason for non-applicability is explained in detail in the permit. 40 CFR 61 Subpart Y: The reason for non-applicability is explained in detail in the permit. 40 CFR 63 Subpart G: The reason for non-applicability is explained in detail in the permit. 35 IAC 219.121: The reason for non-applicability is explained in detail in the permit. 35 IAC 219 Subpart RR: The reason for non-applicability is explained in detail in the permit. 40 CFR Part 64: The reason for non-applicability is explained in detail in the permit. 40 CFR 63 Subpart FFFF specifically §63.2470: The reason for non-applicability is explained in detail in the permit.
Periodic Monitoring (other than basic regulatory requirements)	
Testing	None
Emissions Monitoring	N/A
Operational Monitoring	Maximum storage temperature which determines the maximum true vapor pressure. Temperature of condenser coolant.

Emission Unit - Santoflex Process Storage Tanks	
Inspections	None
Recordkeeping	Both the state rules and NESHAP listed above have detailed recordkeeping requirements.
Other	
Reporting	
Prompt Reporting	Emissions exceeding limits in condition 7.2.3(c). Maximum true vapor pressure exceeding the limit in Condition 7.2.5(a).
Other Reporting	40 CFR 63 Subpart FFFF
Other Information	
Footnotes	
Other	Note that in quoting some applicable state rules for recordkeeping the rule may state that records need to be kept for a minimum of three years. This does not relax the general CAAPP requirement that records be kept for five years.

Table 3 (Section 7.3 of the draft permit)

Emission Unit - P2S5 Process	
Description	Phosphorus pentasulfide (P2S5) is formed into flakes for packaging by reacting phosphorus and sulfur. The P2S5 Process Furnace is used to heat a material used in the P2S5 manufacturing process.
Date Constructed	Although some units were constructed in 1958, for purposes of the PM rule this process is subject to the new units part of the rule.
Emission Control Equipment	The packaging scrubber is classified as an emission unit.
Applicable Rules and Requirements	
Emission Standards	35 IAC 212.123(b) for opacity. 35 IAC 212.321 for PM emissions. 35 IAC 214.301 for SO2 emissions.
Streamlining	

Emission Unit - P2S5 Process	
Title I Conditions	The draft permit contains limits on operation and emissions in Conditions 7.1.5 and 7.1.6. These limits were incorporated from Permit 02030055. The limits in the above permit are considered to be T1R conditions as they were revised from the original construction permit. The change did not increase the total emissions but combined several into one limit. The total is a natural minor increase and not for the purpose of avoiding PSD.
Non-applicability	35 IAC 216.121: The reason for non-applicability is explained in detail in the permit. 35 IAC 217.141: The reason for non-applicability is explained in detail in the permit. 35 IAC 215.301: The reason for non-applicability is explained in detail in the permit. 40 CFR Part 64: The reason for non-applicability is explained in detail in the permit.
Periodic Monitoring (other than basic regulatory requirements)	
Testing	Emission tests may be requested for compliance with the PM, opacity or visible emissions rules.
Emissions Monitoring	N/A
Operational Monitoring	Observe the opacity of the three units weekly.
Inspections	Periodic inspection and prompt repair of defects of the packaging scrubber.
Recordkeeping	Good operating practices and inspections. Opacity readings. Emissions.
Other	
Reporting	
Prompt Reporting	Exceeding the limits in Condition 7.3.3 or 7.3.6. Discovery that any of the basis for nonapplicability are no longer valid.
Other Reporting	N/A
Other Information	
Footnotes	

Emission Unit - P2S5 Process	
Other	<p>Although the SO2 rule was quoted as applicable because sulfur is a raw material, there is no oxygen/air in the reactor that can result in the formation of SO2 and thus the potential for SO2 emissions is extremely low. Therefore no monitoring or recordkeeping to verify compliance with that rule is required.</p> <p>Note that phosphorus compounds are considered to be HAPs but that there is no proposed NESHAP for this industry probably because the emissions are very low.</p>

Table 4 (Section 7.4 of the draft permit)

Emission Unit - ACL Process	
Description	<p>In the ACL process, trichloro-s-triazenetrione (ACL-90) and sodium cyanurate are produced in a continuous process which consists of seven main steps: purification; feed preparation; scrubbing, chlorination and recovery operations; filtering, drying, and cooling; compaction; packaging; and waste treatment. The major raw materials used in the process are cyanuric acid, sulfuric acid, sodium hydroxide, chlorine, and sodium thiosulfate. The final product is shipped primarily to repackers who tablet and/or reformulate and tablet the product.</p> <p>Because one of the main raw materials (cyanuric acid) and the product has several carbon atoms the process is classified by the owner of the process as an organic chemical manufacturing process and therefore the process becomes subject to the MON when it becomes applicable in May 2008. However, both cyanuric acid and the product are solids/powders they are not emitted as volatile organic HAPs (but as PM) and thus the part of the MON that applies only to volatile organic HAPs are not applicable. Another of the raw materials (chlorine, a chemical in the general classification as a halogen or halide) is a HAP and thus the parts of the MON that apply to halide emissions are applicable.</p>
Date Constructed	The numerous pieces of equipment have been replaced over the years and construction dates vary from 1972 to the present.
Emission Control Equipment	Scrubbers and dust collectors
Applicable Rules and Requirements	
Emission Standards	<p>35 IAC 212.123(b) for opacity. 35 IAC 212 Subpart L (§212.321). 40 CFR 63 Subpart FFFF (the MON, effective in May 2008).</p>

Emission Unit - ACL Process	
Streamlining	N/A
Title I Conditions	The draft permit contains limits on operation and emissions in Conditions 7.1.5 and 7.1.6. These limits were incorporated from Permit 92050073.
Non-applicability	35 IAC Part 217, Subparts B and C: The reason for non-applicability is explained in detail in the permit. 35 IAC Part 216.121: The reason for non-applicability is explained in detail in the permit. 35 IAC 215.301: The reason for non-applicability is explained in detail in the permit. 40 CFR 63.2455: The reason for non-applicability is explained in detail in the permit. 40 CFR 63.2460: The reason for non-applicability is explained in detail in the permit. 40 CFR 63.994(b)(2): The reason for non-applicability is explained in detail in the permit. 40 CFR 63.2465(d): The reason for non-applicability is explained in detail in the permit.
Periodic Monitoring (other than basic regulatory requirements)	
Testing	40 CFR 63 Subpart FFFF testing procedures for the halogen scrubber which cite another NESHAP (Subpart SS) test method. The methods to be used for PM testing are specified but there are no specifications for frequency.
Emissions Monitoring	N/A
Operational Monitoring	40 CFR 63 Subpart FFFF for the two scrubbers which control the chlorine emissions. These wet scrubbers can also control any PM emissions that go through the dust collectors. The NESHAP requires pH monitoring and flow meters for scrubbant flow. The actual range of values that assure compliance will be determined during the initial performance test when the rule becomes effective in May 2008. Weekly visible emissions observations of the scrubbers.
Inspections	Dust collector bags every six months.
Recordkeeping	NESHAP recordkeeping per 40 CFR 63 Subpart FFFF, A and SS. Inspections and maintenance of control equipment. Standard operation and emission records. Malfunction and breakdown records.
Other	
Reporting	
Prompt Reporting	PM or visible emissions in excess of limits in Condition 7.1.3. NO _x , PM, chlorine or ammonia in excess of the limits in Condition 7.4.6.

Emission Unit - ACL Process	
Other Reporting	NESHAP reporting. Malfunction reporting.
Other Information	

ATTACHMENT 3: Prompt Reporting of Deviations

Prompt reporting of deviations is critical in order to have timely notice of deviations and the opportunity to respond, if necessary. The effectiveness of the permit depends upon, among other important elements, timely and accurate reporting. The Illinois EPA, USEPA and the public rely on timely and accurate reports submitted by the Permittee to measure compliance and to direct investigation and follow-up activities. Prompt reporting is evidence of a Permittee's good faith in disclosing deviations and describing the steps taken to return to compliance and prevent similar incidents.

Any occurrence that results in an excursion from any emission limitation, operating condition, or work practice standard as specified in this CAAPP permit is a deviation subject to prompt reporting. Additionally, any failure to comply with any permit term or condition is a deviation of that permit term or condition and must be reported to the Illinois EPA as a permit deviation. The deviation may or may not be a violation of an emission limitation or standard. A permit deviation can exist even though other indicators of compliance suggest that no emissions violation or exceedance has occurred. Reporting permit deviations does not necessarily result in enforcement action. The Illinois EPA has the discretion to take enforcement action for permit deviations that may or may not constitute an emission limitation or standard or the like, as necessary and appropriate.

Section 39.5(7)(f)(ii) of the Illinois Environmental Protection Act, which mirrors 40 CFR 70.6(a)(3)(iii)(B), requires prompt reporting of deviations from the permit requirements. The permitting authority (in this case, Illinois EPA) has the discretion to define "prompt" in relation to the degree and type of deviation likely to occur. Furthermore, Section 39.5(7)(f)(i) of the Illinois Environmental Protection Act, which mirrors 40 CFR 70.6(a)(3)(iii)(A) requires that monitoring reports must be submitted at least every 6 months. Therefore, USEPA generally considers anything less than 6 months to be "prompt" as long as the selected time frame is justified appropriately (60 Fed. Reg. 36083, 36086 (July 13, 1995)).

The USEPA has stated that, for purposes of administrative efficiency and clarity, it is acceptable to define prompt in each individual permit. *Id.* The Illinois EPA has elected to follow this approach and defines prompt reporting on a permit by permit basis. In instances where the underlying applicable requirement contains "prompt" reporting, this frequency or a shorter frequency of reporting is the required timeframe used in this permit. Where the underlying applicable requirement fails to explicitly set forth the timeframe for reporting deviations, the Illinois EPA has developed a structured manner to determine the reporting approach used in this permit.

The Illinois EPA generally uses a time frame of 30 days to define prompt reporting of most deviations. Also, for certain permit conditions in individual permits, the Illinois EPA may require an alternate timeframe that is less than 30 days if the permit requirement justifies a shorter reporting time period. Under certain circumstances, EPA may establish a deviation reporting period longer than 30 days, but, in no event exceeding 6 months. Where it has established a deviation reporting period other than 30 days in an

individual permit (specifically Section 7.x.10), the Illinois EPA has explained the reason for the alternative timeframe. (See Attachment 2 of this Project Summary.)

The timing for certain deviation reporting may be different when a source or emission unit at a source warrants reporting to address operation, independent of the occurrence of any deviations. This is the case for a source that is required to perform continuous monitoring for the emission unit, for which quarterly or semi-annual "monitoring" reports are appropriate. Where appropriate, reporting of deviations has generally been combined in, or coordinated with these quarterly or semi-annual reports, so that the overall performance of the plant can be reviewed in a comprehensive fashion. This will allow a more effective and efficient review of the overall performance of the source by the Illinois EPA and other interested parties, as well as by the source itself.

At the same time, there are certain deviations for which quicker reporting is appropriate. These are deviations for which individual attention or concern may be warranted by the Illinois EPA, USEPA, and other interested parties. Under this scenario, emphasis has been placed primarily on deviations that could represent substantial violations of applicable emission standards or lapses in control measures at the source. For these purposes, depending on the deviation, immediate notification may be required and preceded by a follow-up report submitted within 15 days, during which time the source may further assess the deviation and prepare its detailed plan of corrective action.

In determining the timeframe for prompt reporting, the Illinois EPA assesses a variety of criteria such as:

- historical ability to remain in continued compliance,
- level of public interest in a specific pollutant and/or source,
- seriousness of the deviation and potential to cause harm,
- importance of applicable requirement to achieving environmental goals,
- designation of the area (i.e., non-attainment or attainment),
- consistency among industry type and category,
- frequency of required continuous monitoring reports (i.e., quarterly),
- type of monitoring (inspection, emissions, operational, etc.), and
- air pollution control device type and operation

These prompt reporting decisions reflect the Illinois EPA's consideration of the possible nature of deviations by different emission units and the responses that might be required or taken for those different types of deviations. As a consequence, the conditions for different emission units may identify types of deviations which include but are not limited to: 1) Immediate (or very quick) notification; 2) Notification within 30 days as the standard; or 3) Notification with regular quarterly or semi-annual monitoring reports.

The Illinois EPA's decision to use the above stated prompt reporting

approach for deviations as it pertains to establishing a shorter timeframe in certain circumstances reflects the criteria discussed as well as USEPA guidance on the topic.

- 40 CFR 71.6(a)(3)(iii)(B) specifies that certain potentially serious deviations must be reported within 24 or 48 hours, but provides for semi-annual reporting of other deviations. (Serious or severe consequences)
- FR Vol. 60, No. 134, July 13, 1995, pg. 36086 states that prompt should generally be defined as requiring reporting within two to ten days of the deviation, but longer time periods may be acceptable for a source with a low level of excess emissions. (intermediate consequences)
- Policy Statement typically referred to as the "Audit Policy" published by the USEPA defines prompt disclosure to be within 21 days of discovery. (Standard for most "pollutant limiting" related conditions)
- Responses to various States by USEPA regarding other States' definition of prompt.

As a result, the Illinois EPA's approach to prompt reporting for deviations as discussed herein is consistent with the requirements of 39.5(7)(f)(ii) of the Act as well as 40 CFR part 70 and the CAA. This reporting arrangement is designed so that the source will appropriately notify the Illinois EPA of those events that might warrant individual attention. The timing for these event-specific notifications is necessary and appropriate as it gives the source enough time to conduct a thorough investigation into the causes of an event, collecting any necessary data, and to develop preventative measures, to reduce the likelihood of similar events, all of which must be addressed in the notification for the deviation.