GREY PAPER

Process Safety Due Diligence in CM Selection

What Pharma and Chemical Companies Should Be Asking Before They Sign the Contract — Not After the Incident

Kenan Stevick, CCPSC

Co-Author, CCPS Guidelines for Process Safety in Outsourced Manufacturing Operations, 2nd Edition (2026)
Co-Author, CCPS Process Safety Leadership from the Boardroom to the Front Line (2019)

May 2026

Executive Summary

In outsourced chemical and pharmaceutical manufacturing, process safety failures do not respect contract boundaries. When an incident occurs at a contract manufacturer's (CM's) facility involving a client's chemistry or process, both parties are drawn into the investigation, the regulatory proceedings, and the litigation — regardless of what the contract says. The contracting company, the CM, or both can bear responsibility. Both frequently contribute to the conditions that make incidents possible.

Due diligence consistently falls short on both sides. Contracting companies select CMs without adequately evaluating process safety capabilities, send incomplete hazard information, and then fail to verify that the CM understands what it has received. CMs accept work without fully evaluating the hazards involved, fail to ask for the information they need, and allow financial pressure to override process safety requirements. The Optima Belle explosion in West Virginia — in which the client was found to bear the greatest financial responsibility despite the explosion occurring at the CM's facility — illustrates precisely how this dynamic plays out in court. It is not an isolated case. The documented history of outsourced manufacturing incidents shows the same failures repeating across industries, geographies, and decades.

The CCPS Guidelines for Process Safety in Outsourced Manufacturing Operations, Second Edition (2026) defines the standard of care for both parties. For contracting companies, that standard begins at CM selection — a structured, four-phase process that includes self-evaluation, process safety screening, in-depth competency assessment, and meaningful site visits. For CMs, the standard includes the right and the responsibility to demand complete process safety information before accepting work, to define their own governance obligations in the contract, and to decline work where the hazard information is inadequate.

Both parties that get this right protect their workers, their operations, and their legal standing. Both parties that get it wrong share the consequences.

The Problem: Due Diligence That Isn't

Every year, chemical and pharmaceutical companies sign contracts with CMs without adequately understanding their process safety capabilities. The procurement team has reviewed the financials. Legal has reviewed the contract language. Someone may have toured the facility. But the questions that matter most for process safety — the ones that shape whether an incident occurs and who is accountable when it does — often go unasked.

The consequences are well documented. In the Optima Belle explosion in West Virginia in 2021, the client was found to bear the greatest financial responsibility even though the explosion

occurred at the CM's facility. The client had sent hazard information. The CM had not reviewed it carefully. The client had not verified that the CM understood it. Neither party had asked the right questions. Both paid the consequences.

> *"Outsourcing does not shift risk — or the responsibility to manage it — away from the client. When adverse events lead to civil lawsuits and regulatory action, all parties to the relationship are drawn in."*

The CCPS Guidelines for Process Safety in Outsourced Manufacturing Operations, Second Edition (2026) is unambiguous: the client bears governance responsibility throughout the outsourced manufacturing project (OMP), from the initial decision to outsource through to contract termination. That responsibility begins at CM selection. Equally, the CM bears responsibility for understanding the hazards it is being asked to manage — and for asking the right questions when the information it receives is incomplete.

THE PATTERN BEHIND THE INCIDENTS

The Optima Belle case is not unique. The documented history of outsourced manufacturing incidents shows the same failure modes repeating across industries and decades:

• **Corden Pharmachem, Cork, Ireland (2008)** — a runaway reaction at a pharmaceutical CM injured two workers, one fatally. The investigation cited inadequate hazard and risk analysis, deficient pressure relief system design, and operating procedures that failed to account for reactive chemical hazards.

• **TriChem Industries, Texas (2018)** — a worker was fatally injured when sodium chlorite underwent exothermic decomposition. The critical hazard — friction sensitivity — was lost as the material moved through the supply chain, with successive intermediary parties generating new Safety Data Sheets that omitted it. TriChem relied on the SDS it received and did not verify independently.

• **MFG Chemical, Georgia (2004)** — a client-approved scale-up of a reactive process resulted in a toxic gas release injuring a worker and affecting 154 community members. Neither the client nor the CM verified that the production-scale reactor's cooling capacity could handle the heat generation rate measured at lab scale.

In each case, the failure was not a mystery. The hazard existed. The gap in understanding was identifiable. The right questions were not asked.

Why Due Diligence Falls Short

Three structural patterns show up repeatedly in outsourced manufacturing incidents — on both sides of the relationship.

Procurement owns the process, but not the hazards

In many organizations, CM selection is driven by procurement, sourcing, and legal functions — teams expert at evaluating cost, capacity, quality systems, and contractual terms, but generally not expert in process safety. The CCPS Guidelines recommend that CM evaluation be carried out by a multi-functional team that includes process safety subject matter experts. In practice, that step is frequently skipped or treated as perfunctory.

The same structural failure appears on the CM side. Technical and operations staff who understand the hazards are often not involved in the contract acceptance decision. Commercial teams accept work without a rigorous evaluation of whether the CM has the competency, infrastructure, and information needed to run the client's chemistry safely.

The information gap runs both ways

Process safety incidents in outsourced manufacturing commonly involve one of three failures: incomplete process safety information (PSI), inadequate hazard and risk analysis, or tasks that fell through the gap between the parties because no one clearly owned them. All three share a common root: the client and CM do not have a shared, complete understanding of the hazards.

The TriChem case illustrates a specific version of this failure: hazard information that existed at the source was lost as the material moved through the supply chain, with successive intermediary parties generating new Safety Data Sheets that omitted it. By the time it reached the CM, the SDS no longer reflected the actual hazards. TriChem did not verify the information independently. A search of a standard reference — Bretherick's Handbook of Reactive Chemical Hazards — would have revealed the friction sensitivity that caused the fatality.

> *"Simply sending the process safety information is not sufficient. The client should make sure the CM understands it. The CM should make sure it has received everything it needs."*

Safety Data Sheets alone are never sufficient process safety information. A common and dangerous SDS gap is the omission of onset temperatures for runaway reactions — the temperature at which an uncontrolled exothermic reaction will self-accelerate to a potentially catastrophic endpoint. Relying on SDSs without independent verification is a documented contributing factor in multiple CM incidents.

Low cost is treated as acceptable risk — when the right question is right cost for the required safety level

When a client considers a low-cost CM, the implicit assumption is often that the savings are worth the tradeoff. What the analysis rarely includes is the process safety gap cost — the cost of a CM that lacks the instrumentation, competency, or management systems to safely run the client's

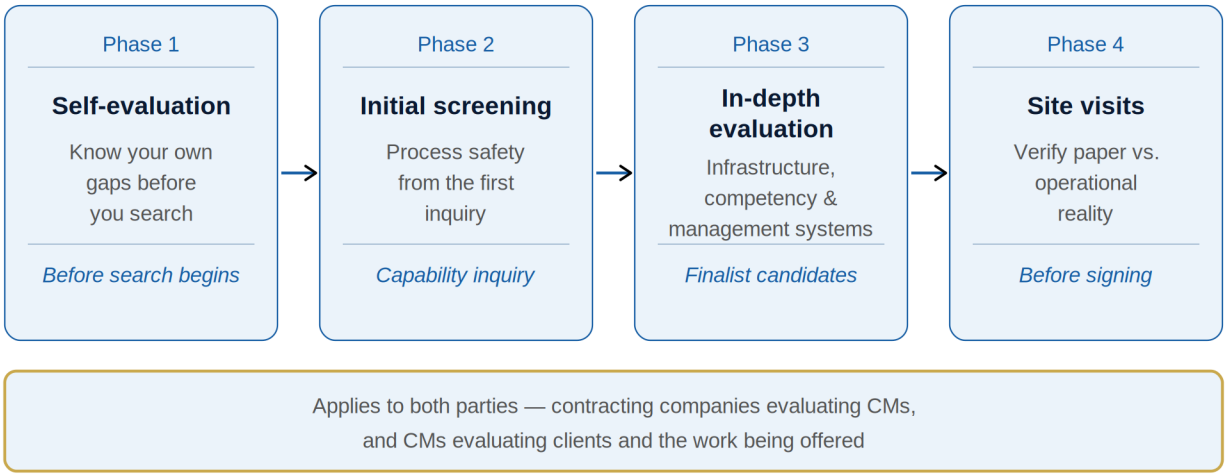
chemistry. The CCPS Guidelines are direct: if a candidate cannot meet the client's minimum criteria for process safety risk and competency, that candidate should be rejected — regardless of cost.

On the CM side, accepting work at a price point that does not support adequate process safety resources is equally problematic. A CM under financial pressure is unlikely to close infrastructure gaps or sustain the staffing and maintenance the work requires.

What Effective Due Diligence Looks Like

Effective process safety due diligence in CM selection is a structured, four-phase process grounded in the CCPS Guidelines and the practical experience of what actually goes wrong. It begins before a CM is contacted and continues through contract execution. It runs in both directions — the client evaluating the CM, and the CM evaluating the client and the work being offered.

Effective process safety due diligence — a four-phase framework



Due diligence continues through contract execution — selection is where it starts, not where it ends

Phase 1: Self-evaluation before the search begins

Before evaluating any CM, a contracting company should evaluate itself. What process safety competencies, tools, and resources does it have in-house? Where are the gaps? Which gaps can a CM reasonably address, and which must the client address regardless? This step is particularly important for companies new to outsourcing and those that have recently undergone significant organizational change — such as divestiture from a larger corporation. Process safety knowledge and management system capability can be lost in a divestiture without anyone recognizing the gap until a problem occurs.

CMs should conduct a parallel self-evaluation before accepting a new class of work. Does the organization have the competency, infrastructure, and management systems to run this chemistry safely? What additional resources would be required? Is the proposed contract price consistent with running the work safely?

SELF-EVALUATION STARTER KIT — QUESTIONS FOR BOTH PARTIES

For contracting companies, before beginning a CM search:

• Do we have complete and verified PSI for this chemistry — including reactive hazard data, onset temperatures, combustible dust characterization, and relief sizing data?

• Have we conducted a process hazard analysis for this process? Are all action items resolved?

• Do we have process safety subject matter experts available to participate in CM evaluation and ongoing governance?

• Has our organization recently undergone a divestiture or reorganization that may have created unrecognized process safety knowledge gaps?

• Can we clearly define the minimum process safety requirements a CM must meet to be considered for this work?

• Do we have a defined governance structure for the OMP — with clear roles, responsibilities, and oversight mechanisms?

For contract manufacturers, before accepting a new class of work:

• Does our facility have the equipment, instrumentation, and utilities required to run this chemistry safely — including appropriate cooling capacity, pressure relief systems, electrical area classification, and inerting systems?

• Do our process safety professionals have demonstrated competency in the specific hazard classes of this chemistry?

• Is the PSI we have received complete and consistent? Have we identified any gaps that must be resolved before we can conduct our own hazard analysis?

• Is the proposed contract price consistent with running this work safely — with adequate staffing, maintenance, instrumentation, and management system resources?

• Do we have a clear escalation path for raising process safety concerns to both our own management and to the client during the OMP?

Phase 2: Initial screening — process safety from the first inquiry

Initial CM screening should go beyond equipment and capacity to address process safety fundamentals. Key areas to include in a contracting company's capability inquiry:

- Process safety incident history — releases of hazardous materials and energy in the past five years, with root causes
- Process safety incident rate and trend data
- Management system structure — completeness of management system scope and elements, how process safety roles and responsibilities are defined and verified

- Specific competency in the hazards relevant to the client's chemistry — reactive hazards, combustible dust, flammability, high-toxicity materials
- Experience with similar chemistry and technology
- Financial health — a CM must have the financial resources to support either existing process safety capabilities or a credible, resourced plan to install the right capabilities for the specific OMP. A CM under financial pressure is unlikely to close infrastructure gaps or sustain the staffing and maintenance the work requires.

The client should also share a screening technology transfer package with candidates — enough information for a CM to demonstrate genuine process safety competency in the relevant chemistry, not just general manufacturing capability.

CMs should use the same inquiry as an opportunity to evaluate the client. Does the client appear to understand the hazards of its own chemistry? Is the PSI it has provided complete and consistent? Has the client clearly defined what process safety governance it expects to exercise during the OMP? A client that cannot answer these questions clearly at the screening stage is signaling a governance gap that will not resolve itself after the contract is signed.

Phase 3: In-depth evaluation of finalist candidates

Once a short list has been developed, a more rigorous evaluation follows. This is where process safety infrastructure, competency, and management system effectiveness need to be assessed seriously.

Process safety infrastructure to assess — existing capabilities or demonstrated ability to install the right capabilities. A CM need not have every required infrastructure element already in place — some may be installed or upgraded for the specific OMP. What must be verified is whether existing infrastructure is adequate, or whether the CM has a credible, resourced plan with demonstrated experience delivering similar capabilities. Specific red flags to watch for:

- Pressure relief systems — are they sized for the worst-case reactive scenario, not just steady-state conditions? The Corden incident involved a reactor that over-pressured because the relief system was not designed for the runaway reaction scenario.
- Cooling systems — is emergency cooling available and hard-piped? Is cooling capacity adequate for the production-scale reaction heat load? The MFG Chemical incident involved a reactor with one-fifth the cooling capacity per unit volume of the pilot reactor — a gap neither party verified.
- Electrical area classification — are process areas classified appropriately for the flammable and combustible materials being handled?
- Safety instrumented systems — are interlocks and emergency shutdown systems in place, tested, and rated for the required safety integrity level?
- Inerting systems — are nitrogen or other inerting systems available and adequate for the chemistry?
- Containment and ventilation — are spill containment, drainage, and ventilation systems appropriate for the hazards?

Process safety competency to assess:

- Clearly defined process safety roles with verified competency in each management system element
- Ability to perform chemical reactivity and combustible dust hazard analyses — can the CM independently verify the hazard data the client provides, and identify gaps?
- Ability to conduct process hazard analyses appropriate to the chemistry and scale
- Evidence that past HIRA findings have been resolved — not just recorded

Management system effectiveness to assess:

- How management of change is handled — does every process or equipment change go through a formal MOC review?
- How incident investigations are conducted and whether findings drive corrective action at the right organizational level
- How audit findings are closed, and whether repeat findings appear across audit cycles
- What governance structure exists for ongoing client oversight

> *The question is not whether a management system exists on paper. It is whether that management system is actually working and producing the desired intent of each management system element.*

Phase 4: Meaningful site visits

Document review is necessary but not sufficient. Site visits are essential for verifying that what a CM has described on paper reflects what is actually happening in the facility. Visits should include process areas, control rooms, maintenance shops, and storage areas — not just conference rooms and presentation decks.

Useful observations include: the physical condition and maintenance state of equipment and instrumentation; evidence of operating discipline (are procedures being followed?); the quality of operating and emergency response procedures; and whether front-line operators can speak to process safety topics in their area. If a CM participates in a third-party assessment program, the client should verify that the infrastructure assessed covers the specific areas of the facility that will be used for the client's process.

The Consequences of Getting It Wrong

The stakes are not abstract. Process safety failures in outsourced manufacturing have killed workers, injured communities, and ended businesses. When due diligence fails at the CM selection stage, the consequences extend well beyond the balance sheet — and well beyond the party whose facility was involved.

For contracting companies, the legal question when an incident occurs is not “whose facility was it?” It is “what governance did the client have over that operation, and was it adequate?” A client that selected a CM without adequate process safety evaluation — without verifying that the CM understood the hazards, and without establishing governance appropriate to the risk — will struggle to answer that question credibly.

For CMs, the legal question is equally pointed: Did the CM have the competency and information it needed to run the client’s chemistry safely? Did it ask for what was missing? Did it raise concerns when the PSI it received was incomplete or contradictory? A CM that accepted work without adequate information, without asking the right questions, and without defining its own process safety obligations in the contract has limited grounds for arguing that the incident was the client’s responsibility alone.

It is also worth noting that regulatory investigations focus on the regulated party — as the Corden investigation did, examining the CM while the client’s role went unaddressed. Civil litigation does not observe the same boundary. When the families of injured workers, affected communities, or insurers pursue recovery, all parties to the relationship are examined.

Beyond litigation, the operational consequences are direct and shared. An incident at a CM facility disrupts supply, damages product, injures workers, generates regulatory attention, and triggers investigations that consume resources on both sides. The best protection — for both parties — is a relationship where the hazards are fully understood, the responsibilities are clearly defined, and the governance is exercised throughout the life of the OMP.

A NOTE ON WHAT FOLLOWS

The following two sections translate the framework above into practical, actionable guidance — first for contracting companies, then for contract manufacturers. Each section can stand alone as a reference tool for the relevant party and is designed to be used before a contract is signed, not after an incident has occurred.

Practical Guidance: For Contracting Companies

The following reflects both the CCPS Guidelines framework and the practical experience of conducting CM due diligence assessments, investigating outsourced manufacturing incidents, and working with legal teams in the aftermath. These are the questions and practices that tend to separate relationships that perform well from those that don't.

Process Safety Due Diligence Checklist — Contracting Companies	
• Conduct a formal self-evaluation of your own process safety competencies and gaps before beginning a CM search. Know what you need the CM to bring before you start looking.	☐
• Assemble a multi-functional evaluation team that includes process safety subject matter experts. Procurement expertise alone is not sufficient.	☐
• Include process safety explicitly in the capability inquiry — incident history, management system structure, and demonstrated competency in the specific hazards of your chemistry.	☐
• Share a screening technology transfer package that gives candidates enough information to demonstrate genuine process safety understanding of your process.	☐
• Evaluate process safety infrastructure, competency, and management system effectiveness in depth — not just equipment lists and quality certifications.	☐
• Conduct site visits that go beyond conference rooms. Observe the facility, talk to operators, and look for evidence of operating discipline in practice.	☐
• Verify that the CM understands the process safety information you have provided. Sending it is a starting point, not an endpoint.	☐
• Do not rely on Safety Data Sheets alone as process safety information. Verify hazard data independently, particularly for reactive hazards and combustible dusts. SDSs frequently omit onset temperatures for runaway reactions.	☐
• Apply minimum process safety requirements as true minimums. A CM that cannot meet them should be rejected, regardless of cost or schedule pressure.	☐
• Define roles, responsibilities, and governance expectations in the contract — and then exercise that governance throughout the life of the relationship.	☐

More detailed process safety due diligence checklists for contracting companies, including specific guidance for each phase of CM evaluation, are available in the CCPS Guidelines for Process Safety in Outsourced Manufacturing Operations, Second Edition (2026).

Practical Guidance: For Contract Manufacturers

CMs are not passive recipients of work. They are process safety stakeholders with their own obligations — to their workers, to the surrounding community, and to the integrity of the relationship they are entering.

Process Safety Due Diligence Checklist — Contract Manufacturers	
• Before accepting new work, evaluate whether your organization has the competency, infrastructure, and management systems to run the client's chemistry safely. If the answer is uncertain, resolve it before signing the contract.	☐
• Review all process safety information provided by the client before committing to the work. Inconsistencies, gaps, and omissions in PSI are red flags, not administrative details to be resolved later.	☐
• Do not accept Safety Data Sheets as complete PSI. Demand the full PSI package — chemical reactivity data, thermal stability data, onset temperatures for runaway reactions, dust explosion data where relevant, and process hazard analysis results.	☐
• Ask the client directly: Has a process hazard analysis been conducted for this process? What were the findings? Have all action items been resolved?	☐
• Evaluate the client's process safety governance posture. A client that has not thought through its own governance obligations is a governance risk for the CM.	☐
• Verify that your facility's infrastructure is adequate for the specific hazards of this work. Specifically verify that pressure relief systems are sized for worst-case reactive scenarios, and that cooling capacity is adequate for the production-scale heat load.	☐
• Define your own process safety obligations explicitly in the contract — what you will do, what you require from the client, and what conditions would require you to stop work.	☐
• Do not accept work at a price point that does not support adequate process safety resources. If the contract economics require cutting corners, the contract economics are wrong.	☐
• Establish a formal process for escalating process safety concerns during the OMP — to both your own management and to the client. A CM that identifies a hazard and does not raise it has accepted ownership of the consequences.	☐
• Remember that your license to operate depends on your process safety record. The due diligence investment at the front end is the cheapest risk management available.	☐

More detailed process safety due diligence checklists for contract manufacturers, including specific guidance for PSI review, hazard analysis requirements, and contract obligations, are available in the CCPS Guidelines for Process Safety in Outsourced Manufacturing Operations, Second Edition (2026).

Questions Worth Asking

The following questions tend to surface the gaps that due diligence is supposed to close. They are the questions that separate a rigorous process safety evaluation from a compliance exercise.

FOR CONTRACTING COMPANIES — BEFORE SIGNING

1. Can this CM demonstrate specific competency in the hazard classes of our chemistry — not just general manufacturing experience?

2. What process safety incidents has this CM had in the past five years, and what did the investigations find? Have the management system failures been corrected?

3. Has the CM reviewed the PSI we provided and confirmed it is complete and sufficient for them to conduct their own hazard analysis?

4. Does this CM's pressure relief system design account for the worst-case reactive scenario for our chemistry — not just steady-state overpressure?

5. Is this CM's cooling capacity at production scale adequate for the heat generation rate of our process? Has this been verified by calculation, not assumption?

6. If we conduct a site visit, will we see the same process safety culture in the operating areas that we see in the conference room?

7. If this CM has a process safety incident involving our chemistry, are we prepared to explain to a regulator or a jury what governance we had over that operation?

FOR CONTRACT MANUFACTURERS — BEFORE ACCEPTING

1. Is the PSI the client has provided complete, consistent, and sufficient for us to conduct our own hazard analysis? If not, what are we missing and how do we get it?

2. Has the client conducted a process hazard analysis for this process? Have we seen the findings and the action item closure status?

3. Are our pressure relief systems designed for the worst-case reactive scenario of this chemistry — or only for our standard operations?

4. Is our cooling capacity at production scale adequate for the heat generation rate of this process? Have we verified this by calculation?

5. Does the client have a defined governance structure for this OMP, with clear roles and responsibilities on both sides?

6. Is our proposed contract price consistent with running this work safely — with adequate instrumentation, maintenance, staffing, and training?

7. If we have a process safety incident involving this client's chemistry, are we prepared to demonstrate that we had the competency, the information, and the governance structures needed to run it safely?

How Kenan Stevick Can Help

Kenan Stevick co-authored the CCPS Guidelines for Process Safety in Outsourced Manufacturing Operations, Second Edition (2026) — the document that defines the current standard of care for client-CM relationships. He brings 44 years of practical experience in process safety, including 34 years at Dow Chemical (Fortune 50) in operational and technical leadership, and direct experience designing and evaluating process safety management systems on both sides of outsourced manufacturing relationships.

For contracting companies evaluating or managing CM relationships, Kenan can design a due diligence process grounded in the CCPS Guidelines, assess whether current practices meet the standard of care, evaluate specific CMs as part of a selection process, or advise on governance structures for ongoing CM oversight.

For contract manufacturers, Kenan can assess process safety readiness for new classes of work, evaluate whether existing management systems meet the standard of care for the chemistry being run, and advise on how to define and protect CM process safety obligations in client contracts.

For legal proceedings involving CM incidents, Kenan can explain what the CCPS Guidelines require of both parties, evaluate whether those requirements were met, and provide expert testimony on the governance and oversight standards they establish — for either side of the relationship.

kenanstevick.com • kenan@kenanstevick.com • 970-409-2528

About the Author

Kenan Stevick is a process safety professional with 44 years of experience in chemical and pharmaceutical manufacturing, including 34 years at Dow Chemical (Fortune 50) in operational and technical leadership. Across two positions, Kenan led the corporate initiative that achieved a cumulative 90% reduction in Tier 1 incidents over ten years — including a 75% reduction in Tier 1 and Tier 2 incidents in his first four years as Chief Process Safety Engineer, preventing more than $50 million in annual incident costs. These results remain industry benchmarks. He co-authored two CCPS publications that define the standard of care in process safety governance: Guidelines for Process Safety in Outsourced Manufacturing Operations, Second Edition (2026) and Process Safety Leadership from the Boardroom to the Front Line (2019). He is a Fellow of CCPS (2015) and holds the CCPS Certified Process Safety Professional (CCPSC) designation. He works with companies on both sides of the outsourced manufacturing relationship — designing programs from the ground up, evaluating management system effectiveness, and providing expert testimony in litigation and regulatory proceedings.

This grey paper draws on concepts and frameworks from the CCPS Guidelines for Process Safety in Outsourced Manufacturing Operations, Second Edition (2026), co-authored by Kenan Stevick and published by the Center for Chemical Process Safety of the American Institute of Chemical Engineers. Case study references: Corden Pharmachem incident — Gakhar et al. (2014), Irish Health and Safety Authority; TriChem Industries incident — Berger (2019), Slack Davis Sanger (2018); MFG Chemical incident — CCPS case study documentation; Optima Belle incident — CSB Final Report No. 2021-02-I-WV (2023). This paper is intended for informational purposes and does not constitute legal advice.