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Rubric for Applying CVSS to Medical Devices

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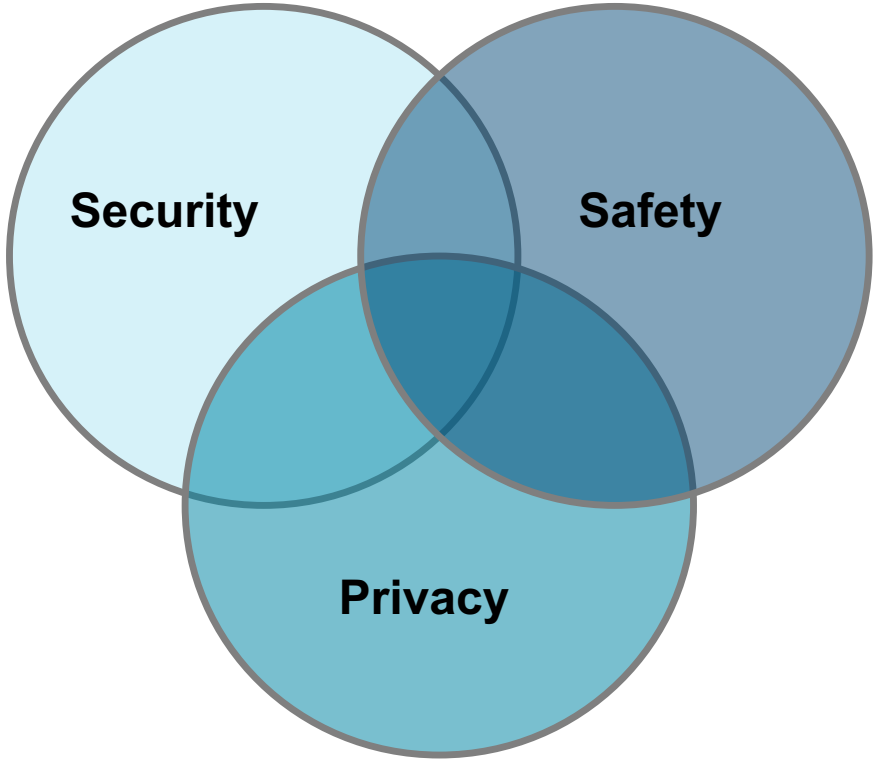
The Delicate Balance of Security, Privacy, and Safety



- **"Everything is a priority"**
- **Varying risks to patient, device, clinical environment**
- **Different regulatory requirements**
- **Different prioritization depending on context of risk assessment**
- **Each can interfere with the other**
  - Don't want anti-virus to fire during surgery
  - Security can erode privacy
- **Our focus: safety and security**

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Challenges in Scoring Real World Vulnerabilities

- **Can be difficult to determine safety impact of a technical finding**
  - Safety regulations already require separation and indirect defense-in-depth
  - Fail-safe operations
- **Vulnerable applications might not directly interact with physical actions**
  - Depends on the functionality and work/data flow
- **Traditional information technology (IT) often prioritizes integrity and confidentiality over availability**
- **For patient safety, availability is often extremely important**
  - "You can't reboot a patient"
- **The clinical environment varies widely**

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Hospira LifeCare PCA3 and PCA5 Infusion Pump

- **Technical vulnerability(ies)**
  - Remote telnet root access without password
  - CVSSv2: 10.0 (ICS-CERT)
- **Healthcare impact**
  - Change drug libraries, including min/max allowed dosage
  - (unproven?) change actual dosage delivered
- **Defense-in-depth:**
  - Human still needs to manually confirm dosage change
- **Environmental considerations**
  - Pump may be on separate, "trusted" network
  - The vulnerable interface might not even be in use
- **Scoring implications**
  - In a hospital performing due diligence, risk may be minimal
- **References**
  - FDA Safety Communication: https://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm446828.htm
  - ICS-CERT Advisory: https://ics-cert.us-cert.gov/advisories/ICSA-15-125-01B

Image from: https://www.hospira.com/en/products_and_services/infusion_pumps/Lifecare

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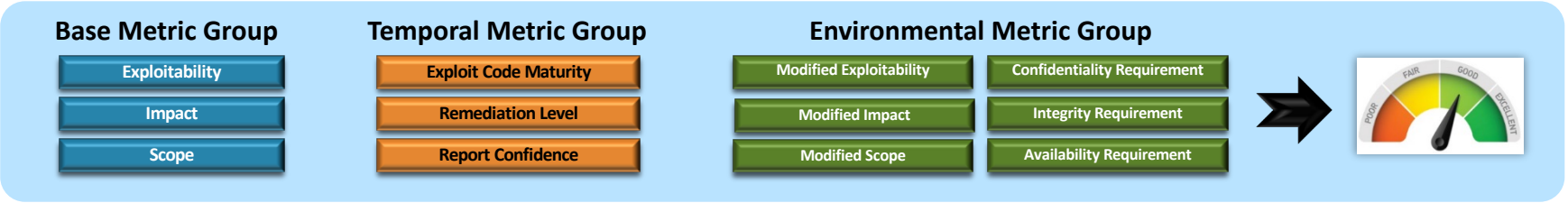
Desired Features for a Healthcare Vulnerability Scoring System

- **Minimal complexity**
- **Usable by – and meaningful to – healthcare practitioners**
- **Accepted by diverse stakeholders**
  - Manufacturers, hospitals, security researchers, patients, regulators
- **Flexible for different clinical environments**
- **Flexible for different device classes**
- **Repeatable, reproducible**
- **Validated**
- **Provide common "language" for centering discussion and keeping disagreements focused**

Common Vulnerability Scoring System (CVSS)



- **CVSS is an open framework developed by the Forum of Incident Response and Security Teams (FIRST) for communicating the characteristics and severity of software vulnerabilities**
  - Base Metric Group: vulnerability's intrinsic qualities
  - Temporal Metric Group: vulnerability's characteristics that change over time
  - Environmental Metric Group: vulnerability's characteristics unique to a user's environment
- **Each vector element is assigned a value and a single score is computed as a weighted sum of those values**

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Approach

- **Established a cross-stakeholder working group: medical device manufacturers, healthcare delivery organizations (HDOs), cybersecurity researchers, FIRST CVSS Special Interest Group, National Cybersecurity Communications & Integration Center (NCCIC), FDA**
- **Reviewed how some manufacturers and healthcare delivery organizations currently use CVSS**
  - Concluded that CVSS is a suitable scoring system, but requires better guidance for use in healthcare settings
- **Developed draft rubric through a series of telcons and email**
- **Conducted initial pilots with manufacturers to validate approach**
- **Submitted a proposal to FDA to qualify as a Medical Device Development Tool (MDDT) and asked to submit a pre-qualification package**
  - A previously validated, scientific tool for use in regulatory decision-making

CVSS Rubric and Extended Vector for Medical Devices

- **The rubric is structured as a series of questions at various decision points for each vector element, and includes**
  - Customized, HDO-specific guidance that is not included in the original specification
  - Device-specific examples
  - Discussion of difficulties in (1) repeatability of the rubric and/or (2) conformance to the spirit of the original CVSS v3 specification
  - Consideration of many perspectives that would be relevant to a medical device manufacturer or an HDO, including (1) patient safety, (2) patient/clinician privacy, and (3) cybersecurity risk from an enterprise vulnerability-management perspective
- **Extended vector records the decisions behind the CVSS vector element**

Rubric: Base Metric Group (Attack Vector) – Questions

- **Q1 (XAVN). Can the attacker utilize some type of network or communication protocol to exploit this vulnerability? Note: Do NOT consider firewall or other access restrictions for this question (see "Working Group Discussion" section).**
- **Yes: Q2 (XAVT). Does the network use OSI layer 3 or 4 protocols, e.g. IP, TCP/IP, or UDP?**
  - **Yes: AV = "N" (Network)**
    - Whether from the Internet or anywhere within the environment's Intranet
    - If there is any access from at least one Internet location
    - Includes access from third-party networks (e.g. manufacturer systems with access to hospital-internal network)
  - **No: Q3 (XAVW). Is the communication over a wireless channel?**
    - **Yes: Q4 (XAVR). Is the range approximately 10 feet or less?**
      - **Yes: AV = "L" (Local). Attacker is physically close to the victim or target, and is presumed to have implied authorization, using short-range communications such as:**
        - Bluetooth LE
        - Zigbee
        - Inductive communication
        - Near Field Communications (NFC)
      - **No: AV = "A" (Adjacent). Attacker is on wireless channel, possibly with a relatively wide range, e.g. network across an entire physical facility or building.**
        - 802.11b

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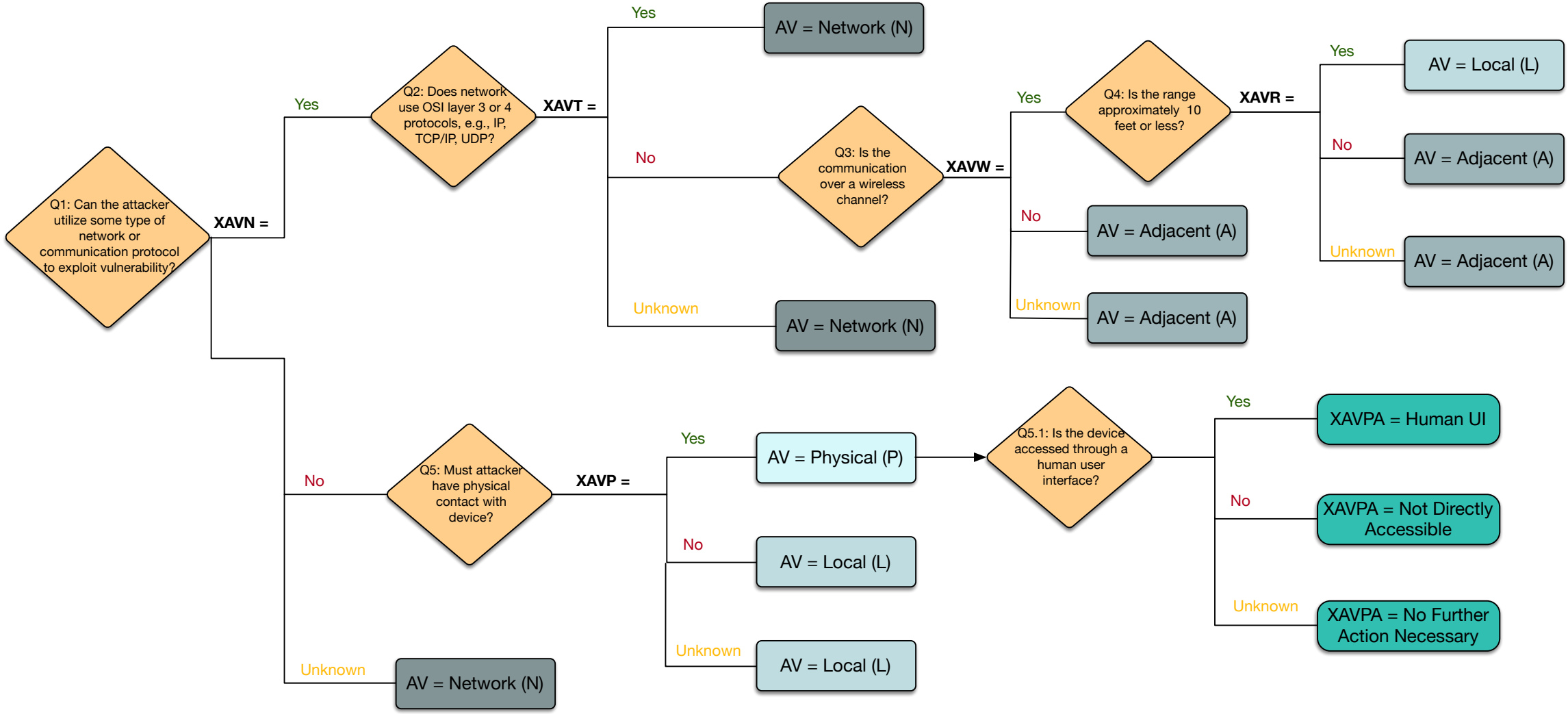
Rubric: Base Metric Group (Attack Vector) – Flow Chart



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Rubric: Base (Attack Vector) – Extended Vector

Question	Element	Values
Q1: Can the attacker utilize some type of network or communication protocol to exploit this vulnerability?	Extended Attack Vector Network (XAVN)	Yes (Y) No (N) Unknown (U)
Q2: Does the network use OSI layer 3 or 4 protocols, e.g. IP, TCP/IP, or UDP?	Extended Attack Vector TCP/IP or UDP (XAVT)	Yes (Y) No (N) Unknown (U) Not Answered (NA)
Q3: Is the communication over a wireless channel?	Extended Attack Vector Wireless (XAVW)	Yes (Y) No (N) Unknown (U) Not Answered (NA)
Q4: Is the range approximately 10 feet or less?	Extended Attack Vector Range (XAVR)	Yes (Y) No (N) Unknown (U) Not Answered (NA)
Q5: Must the attacker have physical contact with the device?	Extended Attack Vector Physical (XAVP)	Yes (Y) No (N) Unknown (U) Not Answered (NA)
Q5.1: Through an intended human UI?	Extended Attack Vector Physical Access Type (XAVPA)	Human UI Not Directly Accessible No Further Action Necessary

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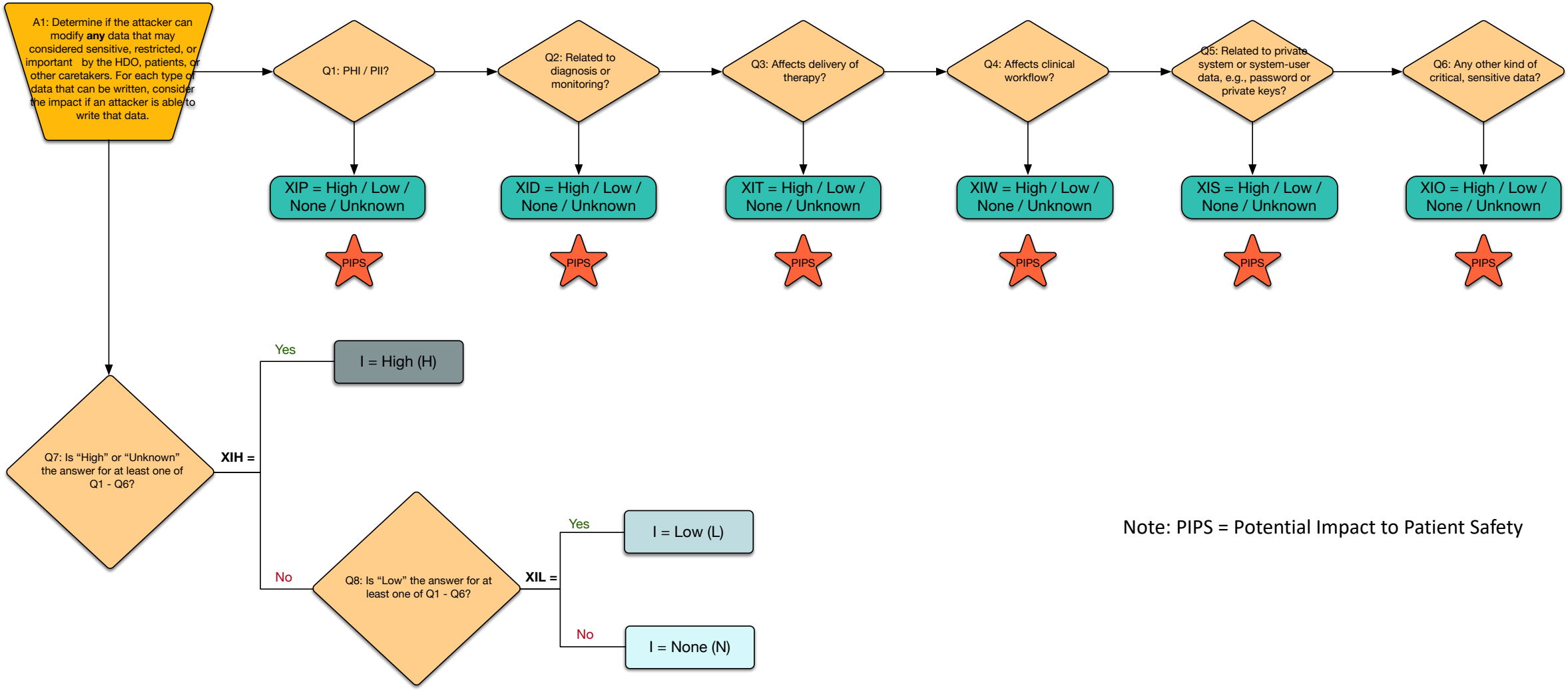
Rubric: Base Metric Group (Integrity Impact)



Note: PIPS = Potential Impact to Patient Safety

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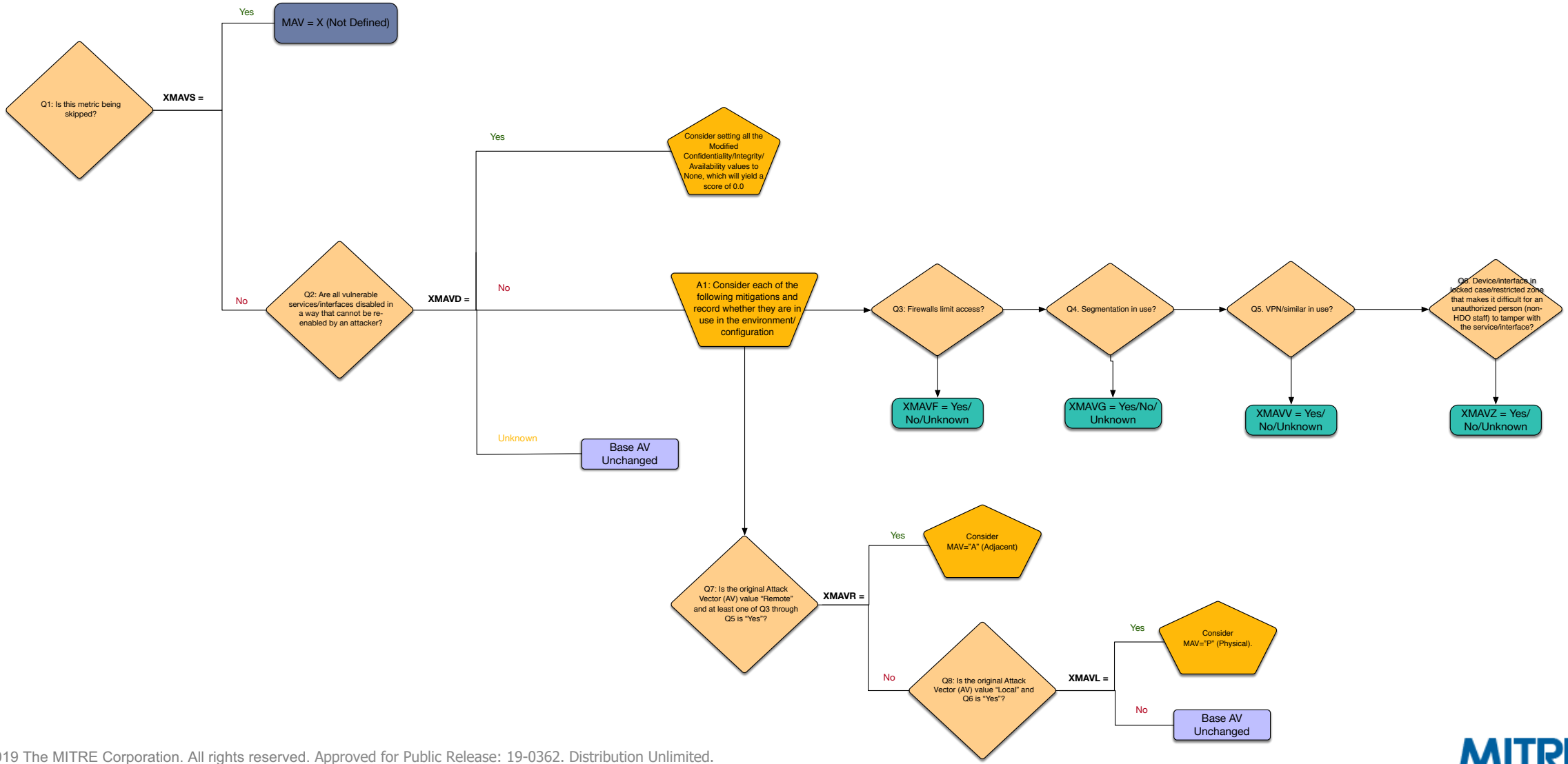
Rubric: Environmental Metric Group (Modified Attack Vector)



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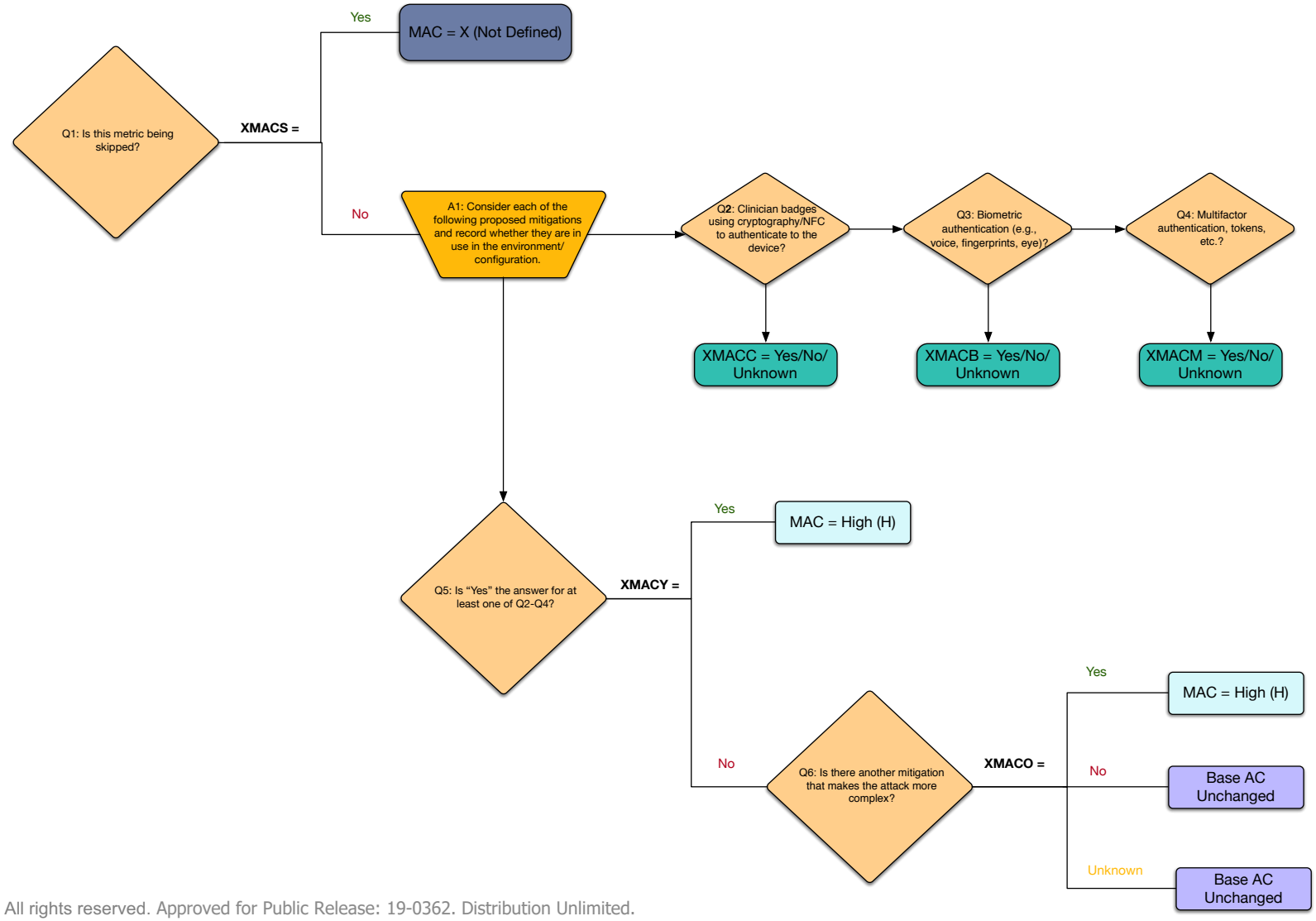
Rubric: Environmental Metric Group (Modified Attack Complexity)



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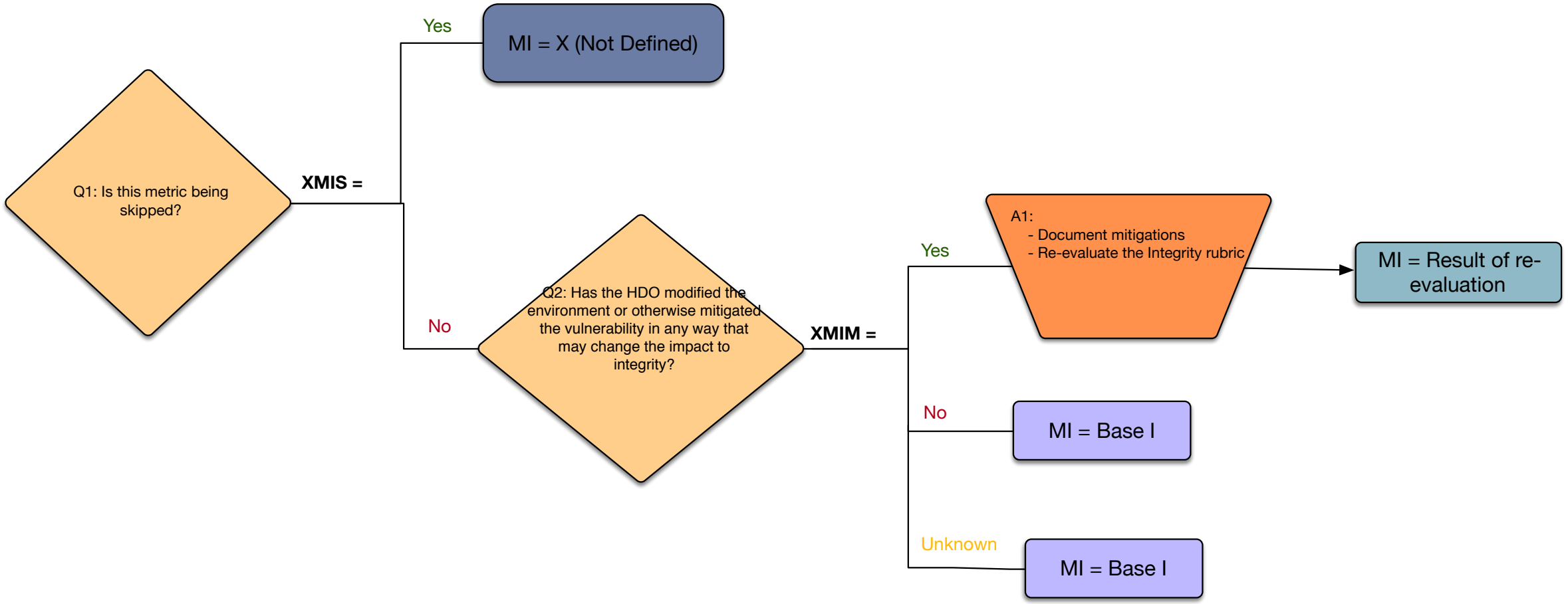
Rubric: Environmental Metric Group (Modified Integrity)



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www.mitre.org/md-cvss-rubric

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Next Steps

- **Develop the MDDT pre-qualification package**
  - Conduct pilots with additional medical device manufacturers to gather additional evidence
    - Demonstrate applicability of rubric to a wider range of devices
    - Assess consistency in scoring
    - Compare rubric vs existing non-rubric scoring process
  - Complete and submit pre-qualification package
- **Develop a calculator**

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