



Global Harmonization Task Force

Working Towards Harmonization in Medical Device Regulation

Training Seminar on Risk Management

Risk Management

from the Perspective of Industry

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Eucomed European Association of the Medical Technology Industry

- Since 1979
- Headquarters: Brussels
- Team of 16
- Members: - 62 Companies
- 25 Associations (also in CEECs)
- Represents over 1500 companies (4500 legal entities)
- Board: - 6 representatives of Companies
- 6 representatives of Associations



IMPROVE patient access to
modern, innovative and reliable
medical technology

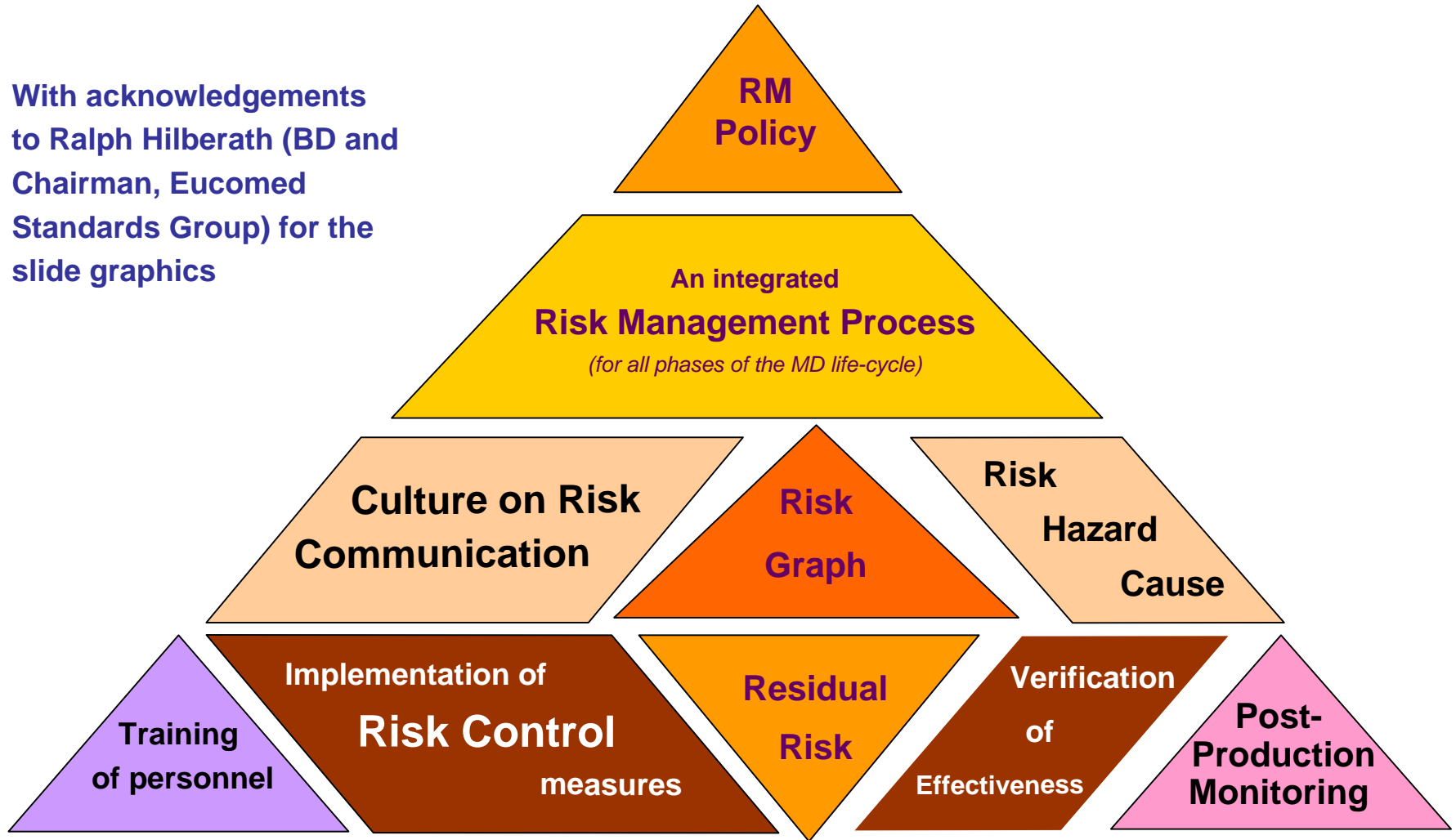
...saving lives

...improving the quality of life



- In this presentation, I will not go into the technical aspects of risk management which have been very well covered by previous speakers
- Rather, I will take a more overall and generic view of the process and explain why, in the medical technology industry, we consider it a crucial tool in relation to:
 - the safety of patients
 - the positive perception of the industry
 - the continuing health of the “new approach” as applied to our industry and the maintenance of a greater degree of self-regulation

With acknowledgements to Ralph Hilberath (BD and Chairman, Eucomed Standards Group) for the slide graphics



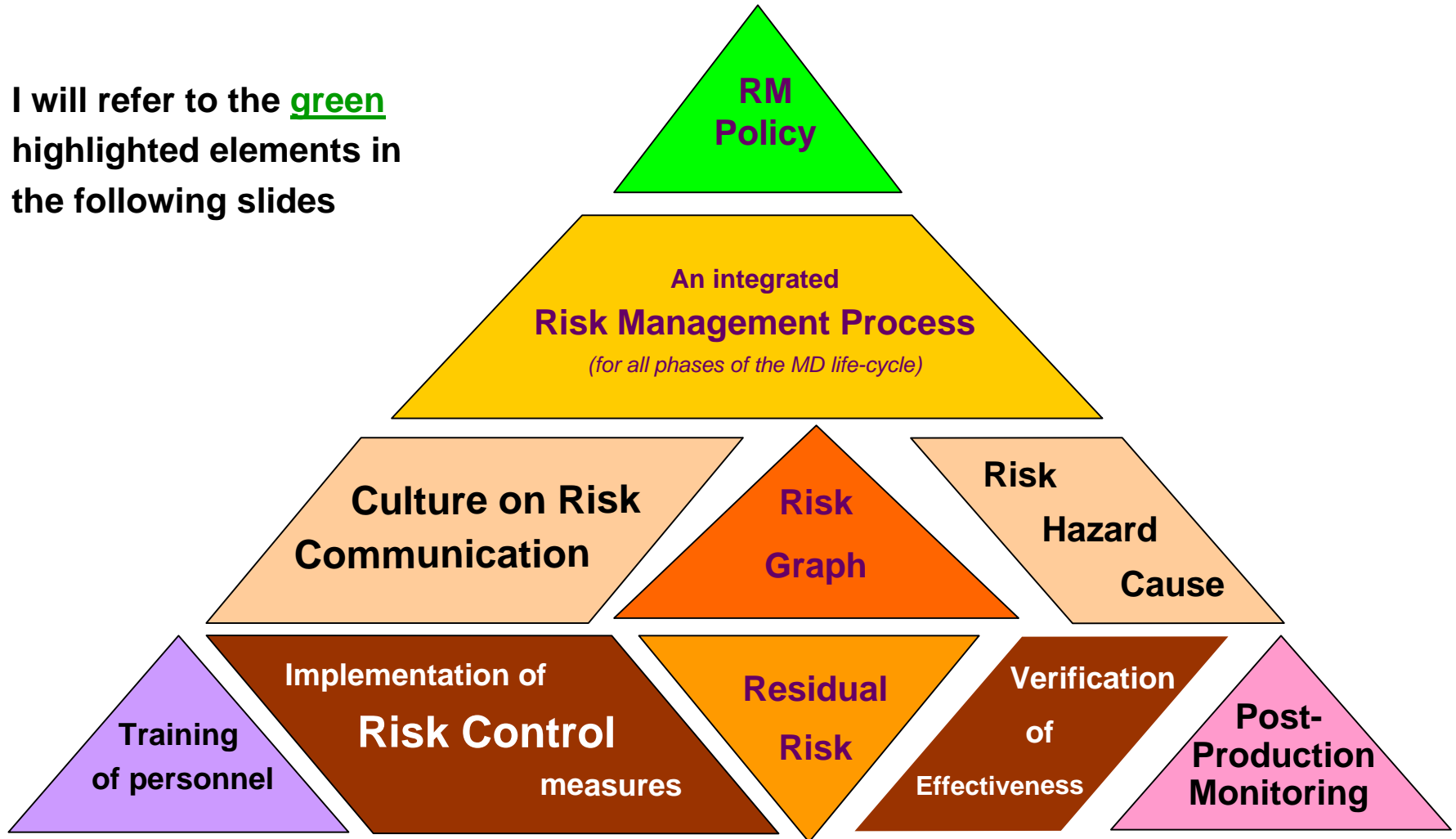


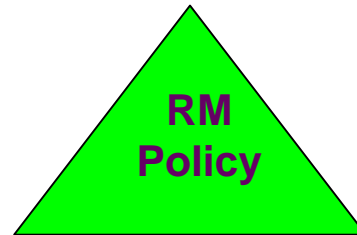
A risk management schematic

F.F.M.

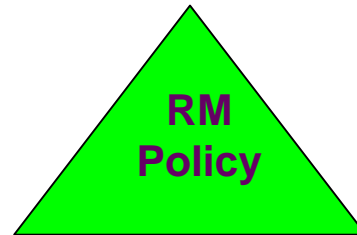
- The previous slide provides a simplified overview of the risk management process and its component and interrelated parts as set out in the standard EN ISO 14971
- During this presentation, I will focus on some critical, but less technical, aspects of the process
- A correct implementation of these less technical, and perhaps slightly more political, aspects of risk management is, nevertheless, crucial in the overall acceptance and understanding by key stakeholders of the validity of the process

I will refer to the green highlighted elements in the following slides

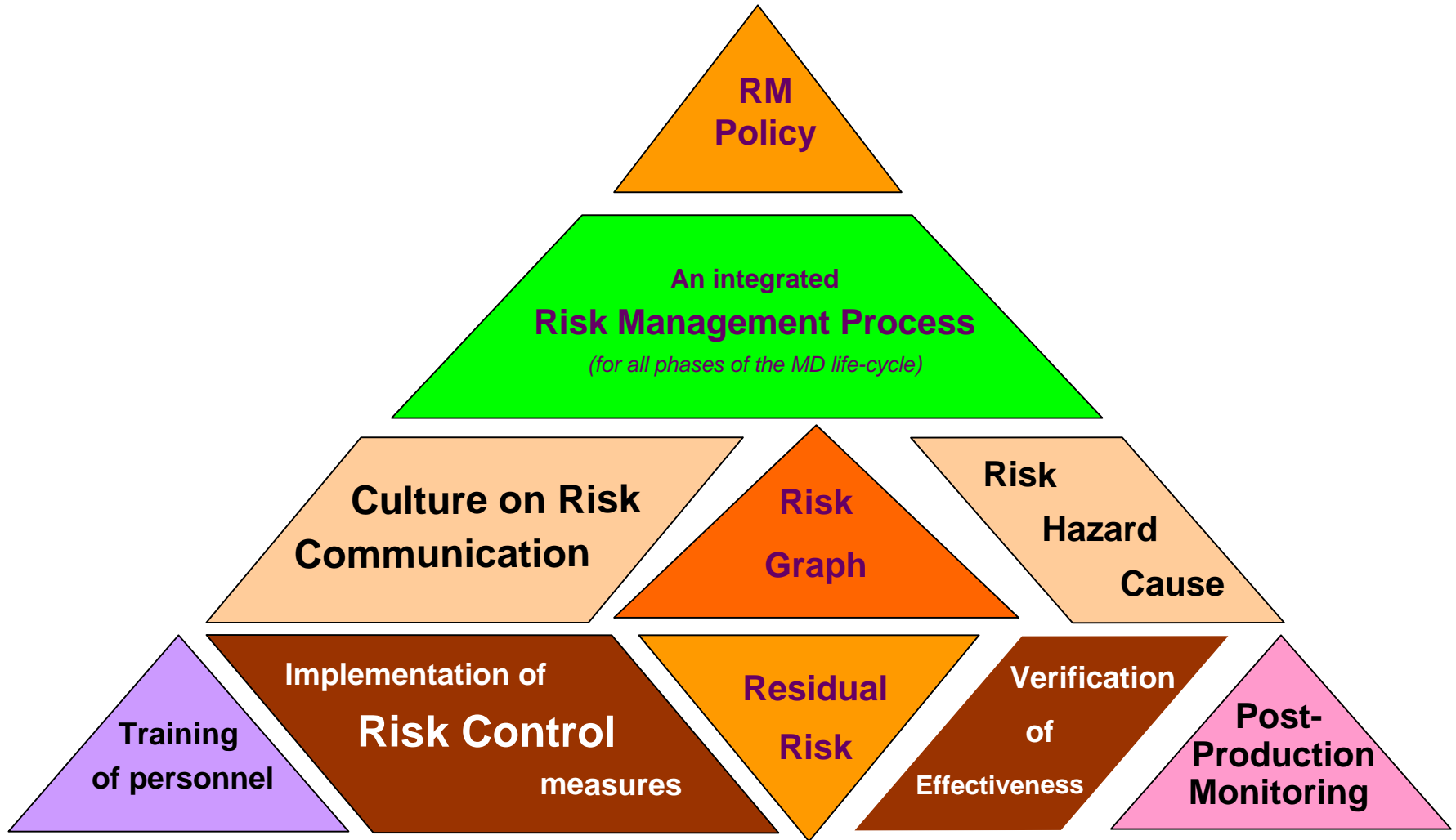




- Developing a coherent risk management policy by a manufacturer is an important requirement of EN ISO 14971 and key to success. Company management responsibilities include:
 - Determining the policy for determining the acceptable level of risk
 - Ensuring the provision of adequate resources for risk management
 - Ensuring the assignment of qualified personnel to the task
 - Reviewing the results of risk management activities at defined intervals to ensure the continuing suitability and effectiveness of the risk management process

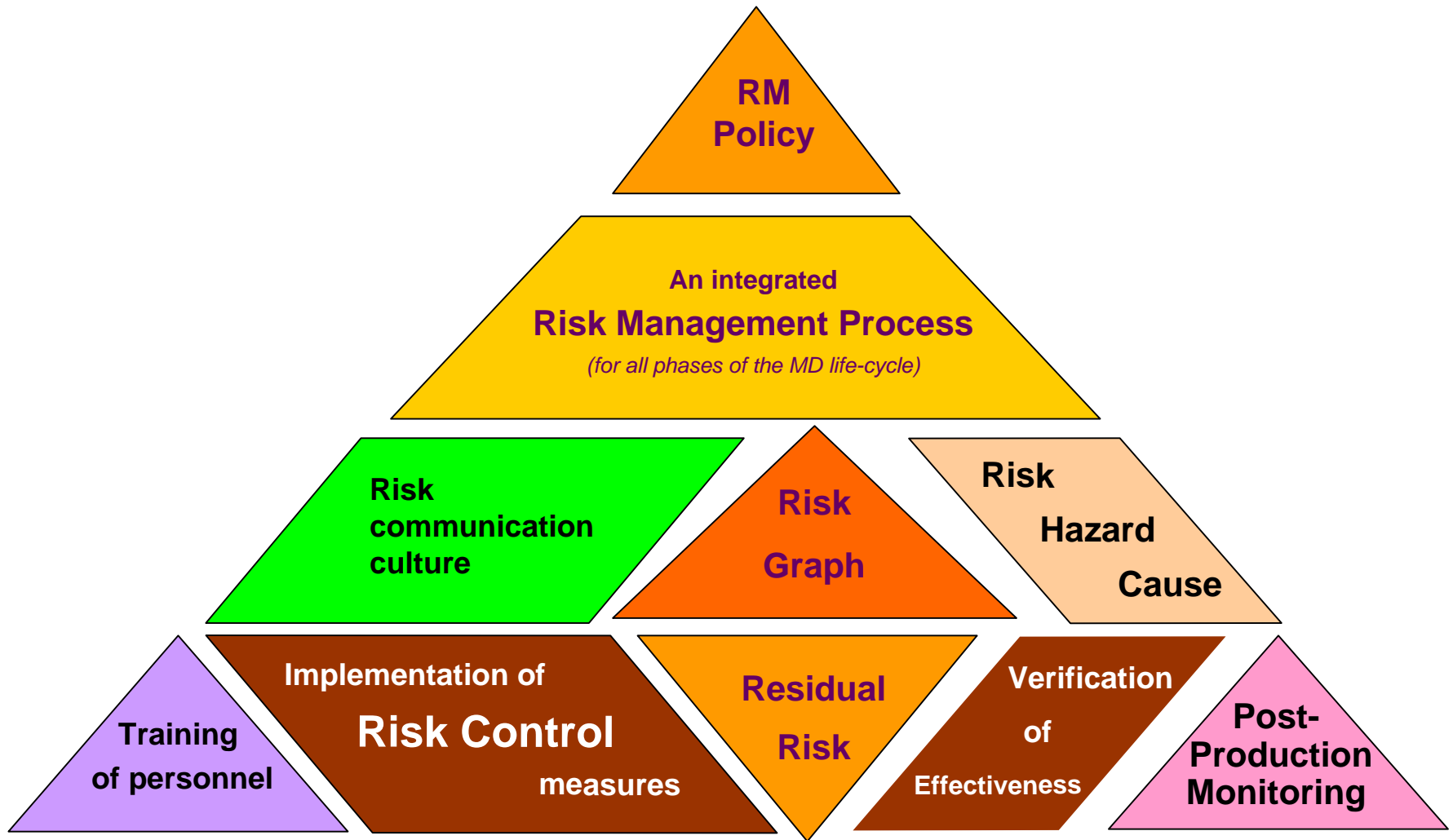


- In addition, the manufacturer has to ensure:
 - That, for a particular medical device, a risk management plan has been prepared
 - That this plan describes the device and its life-cycle
 - That responsibilities and authority are assigned
 - That measures are in place for verification
 - That criteria for risk acceptability have been defined
 - That measures are in place for obtaining relevant post-production information that is to be fed back into the risk management process





- I will not go into the detailed technicalities of the risk management process but an interesting word here is “integrated”
- This implies that the risk management process should be fully integrated into the daily working practices and culture of the company
- It is permissible, and often desirable, to integrate the risk management process into other key company processes like quality systems





- This is an interesting aspect of the risk management process and one that has been much debated within the ISO/IEC Joint WG
- A key question for manufacturers must be: “To what extent can I/should I try to influence risk matters outside my direct control?”
- Some manufacturers have adopted the view that, legally, their risk communication should be strictly limited to that specified by the medical device directives



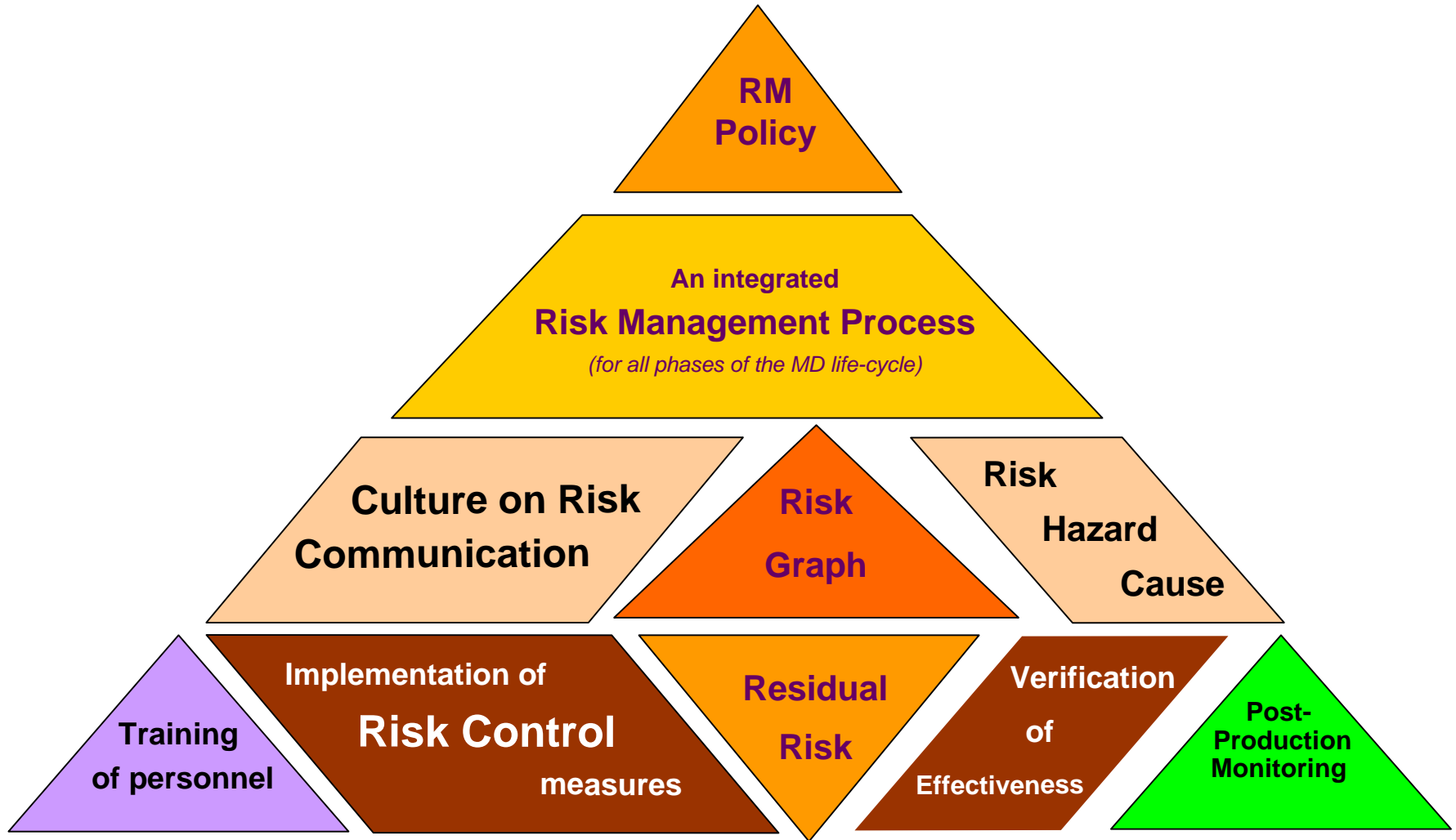
- However, events such as the recent Patient Safety Conference in Luxembourg have convinced Eucomed that there may be a need to further explore the extent to which risk issues are communicated
- Patients and, especially, their doctors are also key elements in the “risk chain”
- In addition, “risk communication” implies not only delivering a message but ensuring that the message is understood

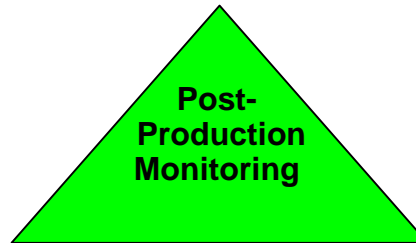


- This is particularly important where critical safety issues are involved
- Two cases where Eucomed has been particularly proactive on this issue are the campaigns on the protection of medical professionals from sharps injuries and against the re-use of single-use devices
- In both cases, Eucomed and its Members have actively engaged in an dialogue with other stakeholders aimed at raising their “risk awareness” cultures

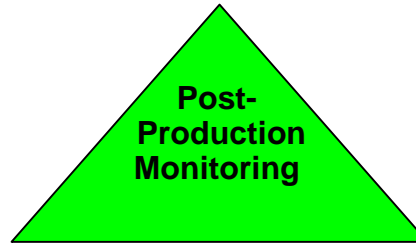


- In many ways, this is also one of the key areas where the medical technology industry becomes “visible” to others
- In a regulatory environment where some regulators are increasingly challenging the “new approach”, it is Eucomed’s opinion that a frank and honest communication of risk issues with stakeholders is vital if the industry is to prove that “it does the job correctly” and has “patient safety” issues as a number one consideration

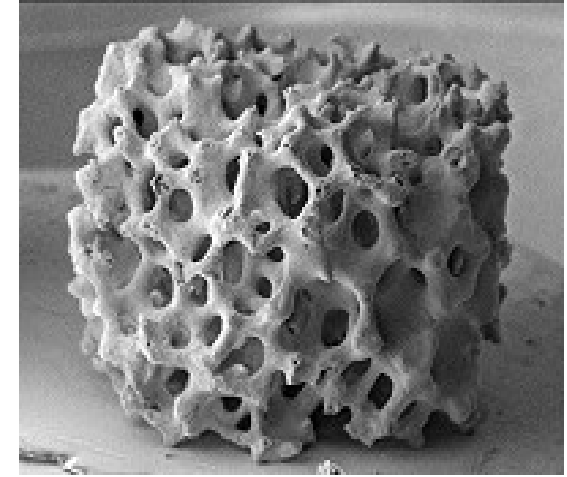
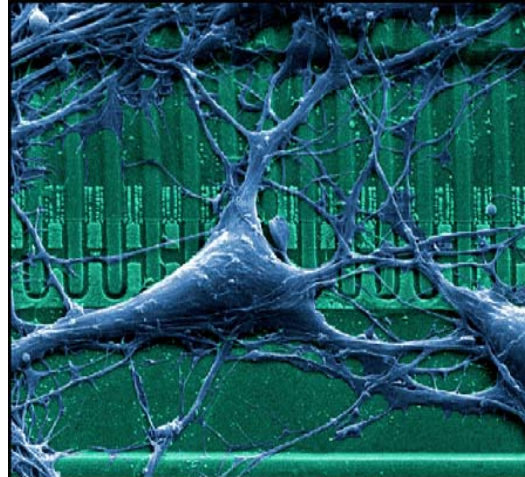




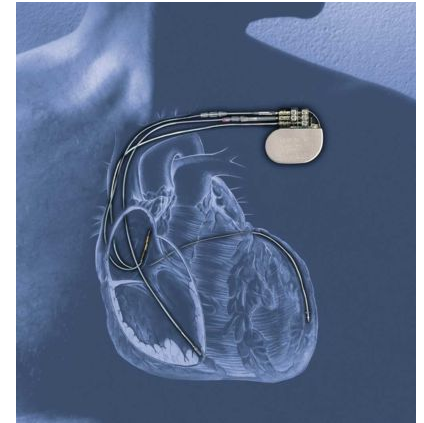
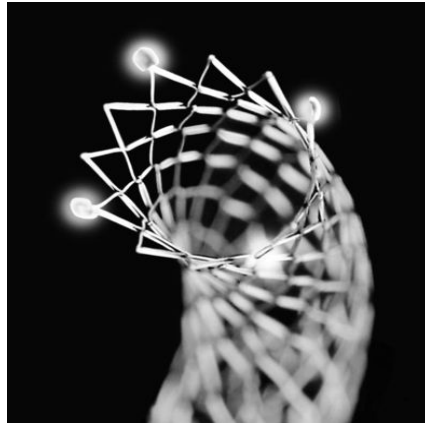
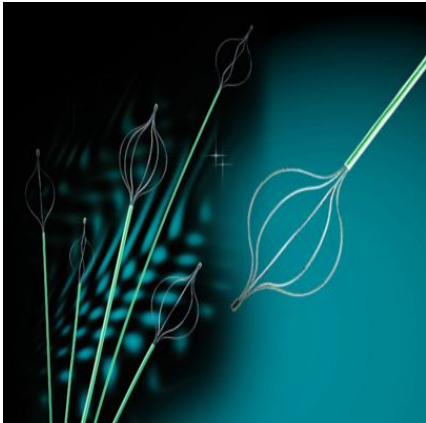
- Post-production monitoring is also a key element for the credibility of the “new approach” and of the risk management process
- A good example of this is the high level of concern, recently raised by doctors’ and patients’ groups at the recent Luxembourg Patient Safety Conference, with Eucomed regarding the high number of adverse incidents reported with IV pumps



- While both pump and syringe manufacturers are diligent with their risk management, both types of device are ubiquitous in hospitals and many different designs and brands are regularly stocked and used
- It is therefore vital that any change or development introduced with one group of devices is clearly communicated to the manufacturers of the other type to ensure continuing compatibility, safety and clear user information. Eucomed is bringing both groups together to facilitate this.



- The medical technology industry is currently in an era of tremendous innovation and rapidly converging technology
- There is a strong need to ensure that future regulation is firmly embedded in the culture of risk management and that as many elements of the innovation- friendly “new approach” system are retained in the light of scepticism of the system from some quarters



- The downside to not doing this effectively is that regulators may be tempted to place new technologies into regulatory regimes that they (mistakenly!) think are “safer” and that are intrinsically unsuitable
- This could have disastrous consequences for bringing the benefits of new technology to patients and for the medical technology industry



- We are now living in an age where demographic shifts and new EU countries bring new challenges to healthcare and where funding and reimbursement, and perception of risk by regulators remain challenges
- Eucomed sees systematic risk management as an essential tool in ensuring patient safety, increasing confidence of key stakeholders and maintaining an efficient and effective regulatory system for the medical technology industry