

TGA's Medical Device Incident Report Investigation Scheme (IRIS)

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What is IRIS ?

- (Medical Device) Incident Report Investigation Scheme.
- “A scheme intended to help maintain the standard of devices used in health care through the voluntary cooperation between users government and industry”
- Through: The investigation of Medical Device Adverse Event Reports.



Adverse Events (Incidents):

- An EVENT (problem, incident, accident, result of testing, observation, etc) that...
 - resulted,
 - could have resulted (had effective intervention not taken place)
 - could result in (in the case of testing, observation)...
- ...in serious injury or death of a patient healthcare worker or other person.



Adverse Events (cont'd)

- Medical Device Adverse Event:
 - An Adverse Event that is associated (caused or partially attributable) with the use (**or misuse**) of a medical device.
- Difficulties and Malfunctions:
 - Problems, repeated repair requests, ease of use, high number of faults that never injured and are not likely to injure, but affect the quality, timeliness and cost-effectiveness of care. (May pre-empt safety concerns)



Sponsors (suppliers) must:

- “Keep a log of problems relating to the condition, use or application of their therapeutic devices.”
- “...report to TGA all deaths, serious illness, serious injuries, arising from or in some way attributable to the use or application of the therapeutic devices.” *(NB: The laws which have recently been introduced also require sponsors to report “near events”)*
- Provide annual summarised reports in respect of problems for the first three years of registration.

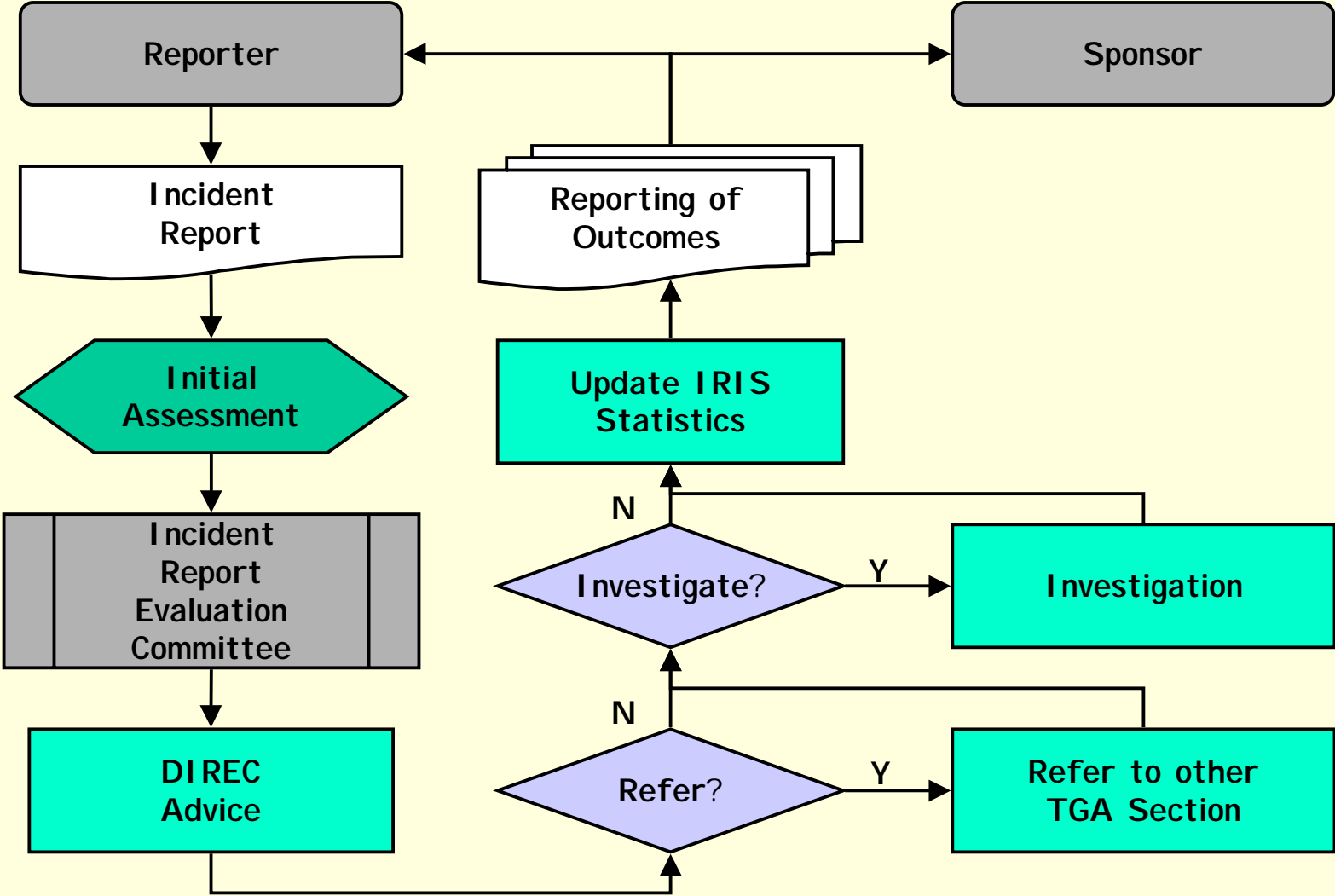


Device users and others are encouraged to report....

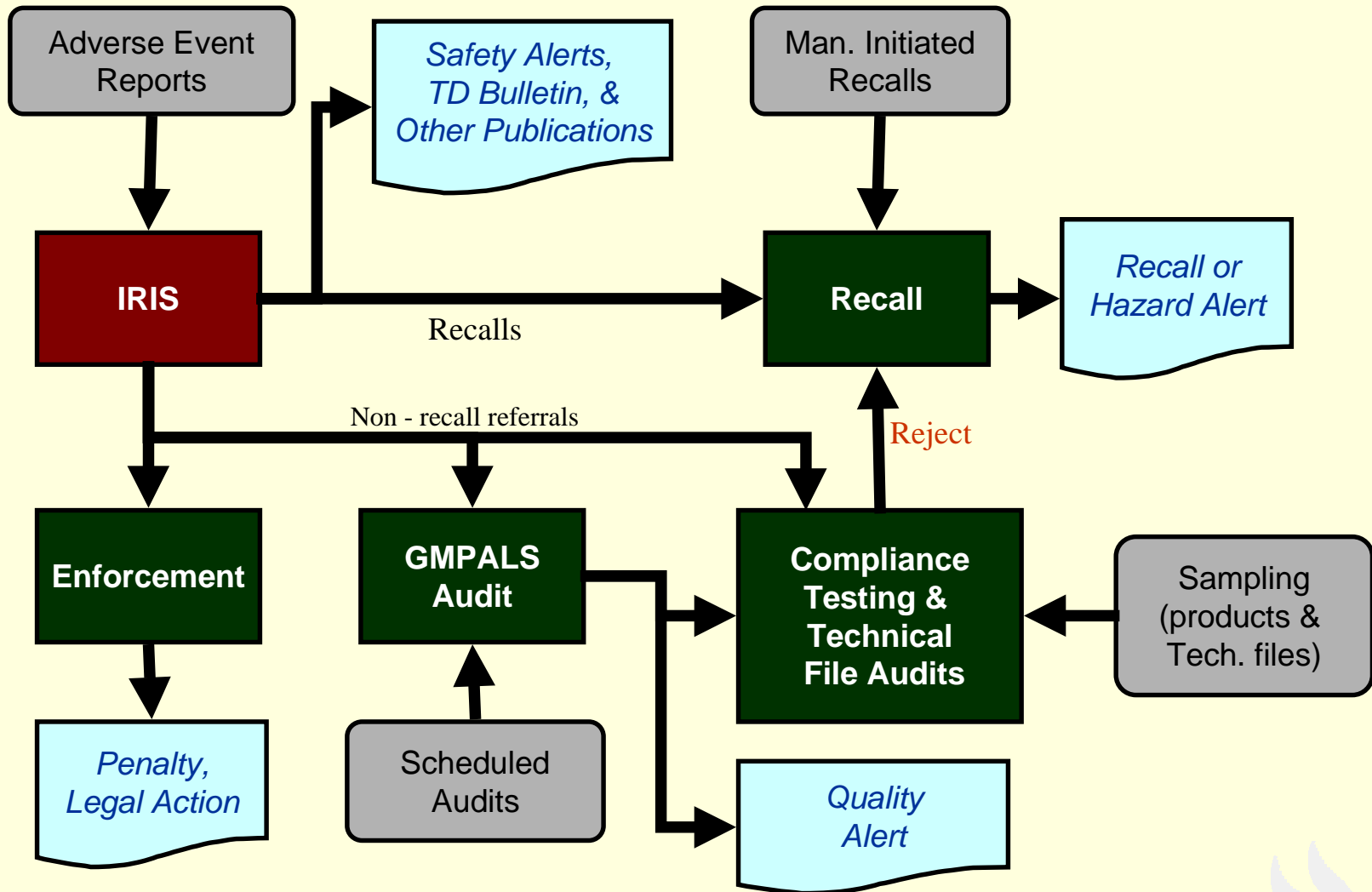
- Events associated with the use of a medical device, that has led, or could have led to serious injury or death.
- Events or other information (eg design assessment) in regards to the quality, efficacy and safety of medical devices



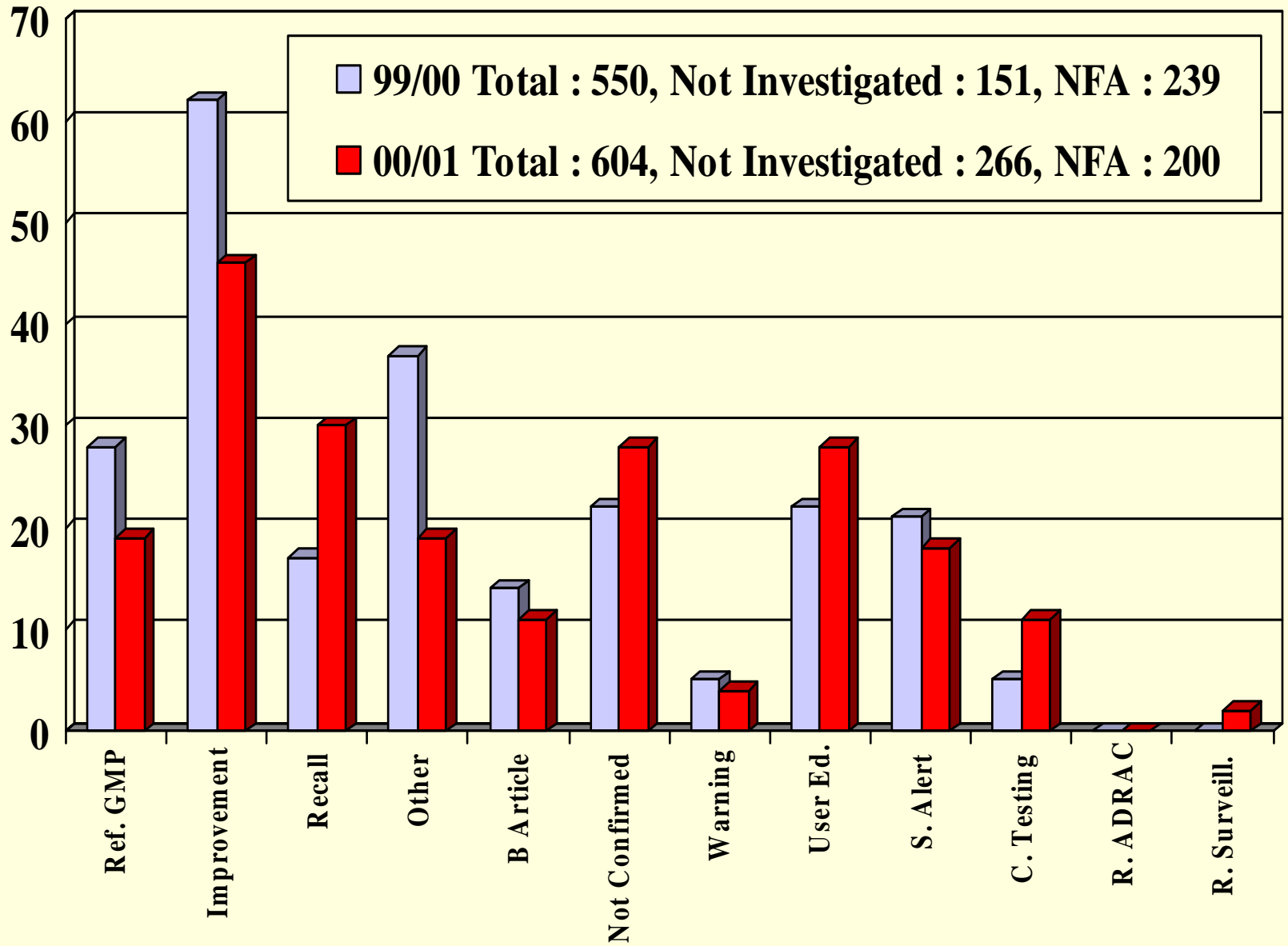
The IRIS process



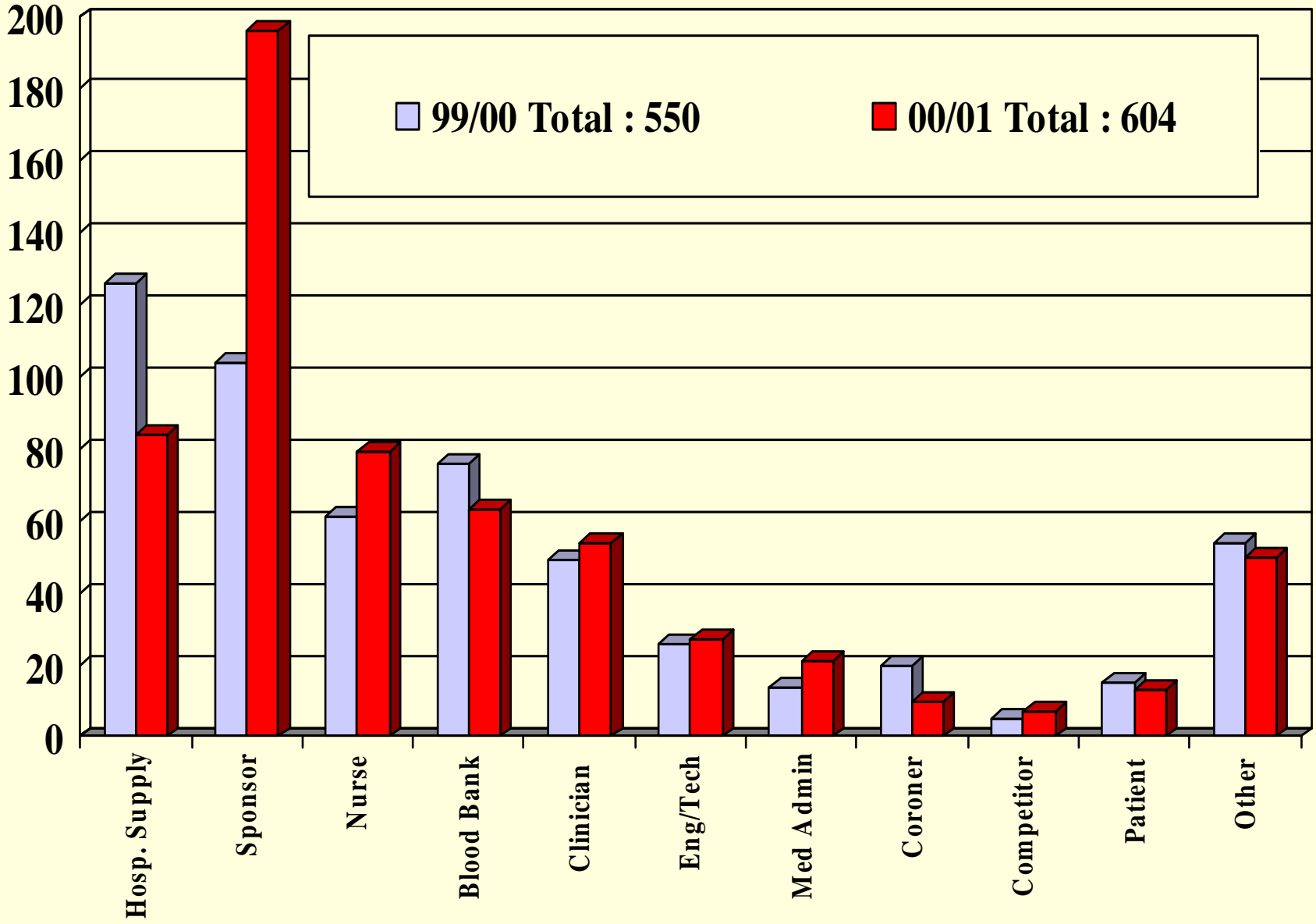
TGA's Post-Market Surveillance Systems



Result of Investigations



Source of Reports



Type of Reports Received

