



Gamma Industry Processing Alliance (GIPA)

Presentation to the USNRC
7 April 2003



Overview

- There is a current shortfall of gamma sterilization capacity in US facilities
 - ▣ demand of product sterilization is growing
 - ▣ current facilities operate 24/7/365
 - ▣ new facilities are ready for ^{60}Co loading
- The healthcare industry must reinforce and build their sterilization capacity
 - ▣ ^{60}Co is available at suppliers facilities
- A suitable mechanism is necessary to enable ^{60}Co shipments under the current security alter conditions



Sterile Single-Use Medical Devices

- 50% of the world's sterile single-use medical devices come from the US
- 40% of the sterile single-use devices used in the US are sterilized by ^{60}Co
- This includes devices for the US military
- There are approximately 132 MCi ^{60}Co installed in the US
- Used to sterilize about 200MM cu. ft. of single-use medical devices annually



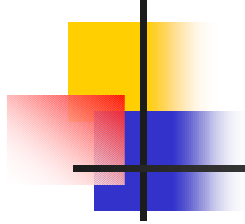
Other Sterilization Methods

- Devices are designed specifically for ^{60}Co sterilization
 - Other sterilization methods may require a design and/or material changes
 - Other sterilization methods would require evaluation and testing
- Changes to products and/or sterilization methods require a new submission to FDA
- Testing to determine appropriate changes, followed by submission review and approvals take months and years not days and weeks



^{60}Co Sterilization Capacity

- Sterilization capacity is based on projected demand (growing 7-15% annually) and isotope decay (currently 16.5 MCi annually)
- No excess ^{60}Co is maintained in irradiators
- There has been a ^{60}Co shortage for the past year
- Irradiators operate on a 24/7 schedule to optimize utilization of ^{60}Co
- Increase in sterilization demand for Health and Human Services would require additional ^{60}Co



Medical Device Inventories

- Most medical device companies practice “Just In Time (JIT)” manufacturing
- Inventories in the order of 30 to 40 days are common
- Low inventories help control healthcare costs
- Disruption of the supply of ^{60}Co will result in backorders of sterile single-use devices



Impact on Healthcare

- Only healthcare providers can define life threatening medical conditions
- Backorders will result in shortages of critical medical devices
- Healthcare facilities do not have substitutes for these medical devices
- Shortages of medical devices can result in irreversible medical complications including death



Summary

- No sterilization capacity in the industry today – this is causing life threatening conditions
- We need to enable ^{60}Co shipments immediately to address this critical healthcare issue