

Restricted by Whom?

*A Historical Review of
Strategies and Organization
for Restricted Earth Return of Samples
from NASA Planetary Missions*

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(Work conducted as a part of ELBI Fellowship/JHU)

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Abstract

This presentation is a review of the timeline for Apollo's approach to Planetary Protection, then known as "Planetary Quarantine." Return of samples from Apollo 11, 12 and 14 represented NASA's first attempts into conducting what is now known as "Restricted Earth Return," where return of samples is undertaken by the Agency with the utmost care for the impact that the samples may have on Earth's environment due to the potential presence of microbial or other life forms that originate from the parent body (in this case, Earth's Moon).

Questions

- Who was involved with back contamination for the first rounds of Apollo missions?

What agencies?

Who selected these agencies?

Terms of Reference?

- Was there any overlap in quarantine policy development and requirements for robotic missions vs. Apollo (forward and backward contamination)? If so, where and how much?
- Who determined when there was enough evidence to deem lunar samples “safe” and crew members “safe” from potential lunar biohazards with terrestrial-equivalent mechanisms?

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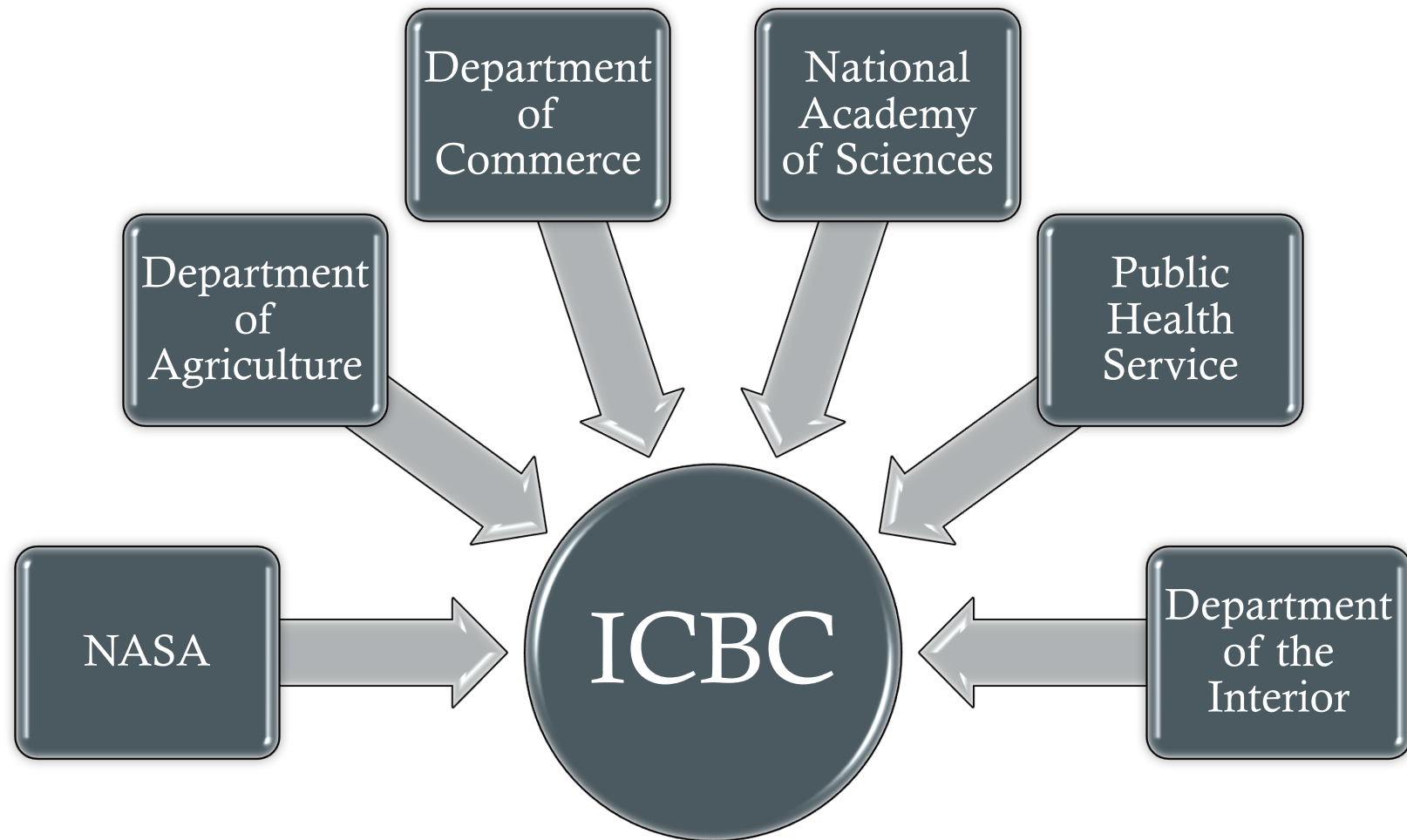
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Then...

NSAM 235 & the Interagency Committee on Back Contamination (ICBC)



NSAM 235

National Security Action Memo 235

When: 1963, Kennedy Administration

Directed to: State, DoD, Interior, Commerce, USDA, Atomic Energy Commission, NSF, Health/Education/Welfare and Special Assistants to the President for National Security Affairs and for Science & Technology

Upshot: Head of Agency requests President's approval via Special Assistant to the President for Science and Technology, with potential input from National Academy of Sciences, international scientific bodies and intergovernmental organizations.

When did NASA used this? Apollo Launches for ICBC and SNAP/RTG (nuclear)

~~CONFIDENTIAL~~

THE WHITE HOUSE
WASHINGTON
April 17, 1963

FILE COPY

NATIONAL SECURITY ACTION MEMORANDUM NO. 235

TO: The Secretary of State
The Secretary of Defense
The Secretary of the Interior
The Secretary of Commerce
The Secretary of Agriculture
The Secretary of Health, Education, and Welfare
The Chairman, Atomic Energy Commission
The Administrator, National Aeronautics and Space Administration
The Director, National Science Foundation
The Special Assistant to the President for National Security Affairs
The Special Assistant to the President for Science and Technology

SUBJECT: Large-Scale Scientific or Technological Experiments with Possible Adverse Environmental Effects

I have approved the following policy guides governing the conduct of large-scale scientific or technological experiments that might have significant or protracted effects on the physical or biological environment. Experiments which by their nature could result in domestic or foreign allegations that they might have such effects will be included in this category even though the sponsoring agency feels confident that such allegations would in fact prove to be unfounded.

1. The head of any agency that proposes to undertake a large-scale scientific or technological experiment that might have significant or protracted effects on the physical or biological environment will call such proposals to the attention of the Special Assistant to the President for Science and Technology. Notification of such experiments will be given sufficiently in advance that they may be modified, postponed, or cancelled, if such action is judged necessary in the national interest.
2. In support of proposals for such experiments, the sponsoring agency will prepare for the Special Assistant for Science and Technology a detailed evaluation of the importance of the particular experiment and the possible direct or indirect effects that might be associated with it.

DECLASSIFIED
E.O. 12356, Sec. 3.4
NLK-93-94
By SKF BWA Del 7/2/93

~~CONFIDENTIAL~~

“mights” and “mays” are enough...

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2. In support of proposals for such experiments, the sponsoring agency will prepare for the Special Assistant for Science and Technology a detailed evaluation of the importance of the particular experiment and the possible direct or indirect effects that might be associated with it.

5. Any experiment that may involve significant or protracted adverse effects will not be conducted without my prior approval.

Process:

1. Agency head notifies Head of Agency requests President's approval via Special Assistant to the President for Science and Technology.
2. Special Assistant to the President for Science and Technology reviews material from Agency
3. Special Assistant to the President for Science and Technology makes recommendation to President
4. Input may be requested from National Academy of Sciences, international scientific bodies and intergovernmental organizations.

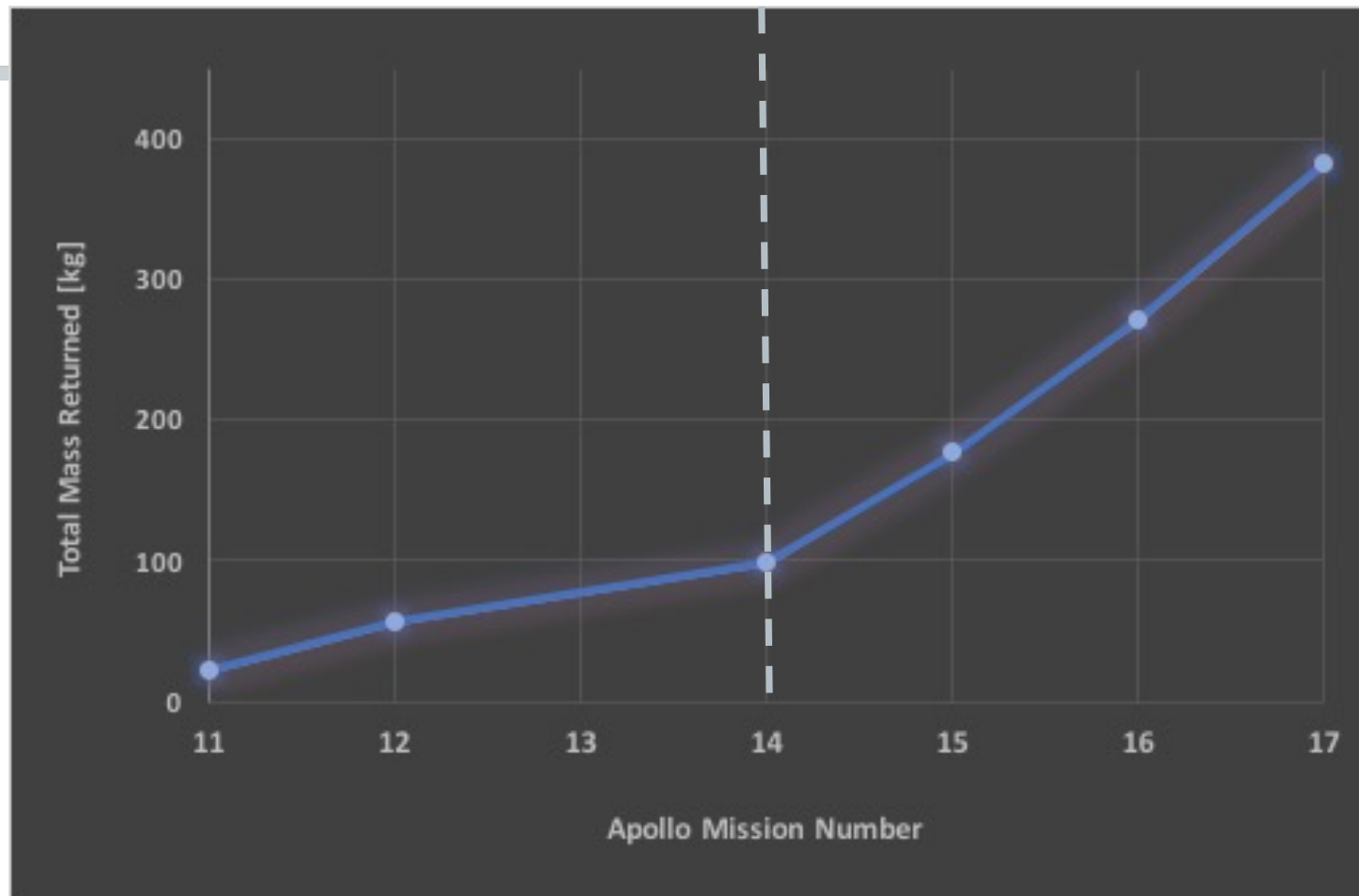
3. The Special Assistant for Science and Technology will review the proposals and supporting materials presented by the sponsoring agency in order to assure that the need for the experiment has been properly weighed against possible adverse environmental effects.

4. On the basis of this review, the Special Assistant for Science and Technology will recommend to me what action should be taken on the proposed experiment. If the Special Assistant judges that inadequate information is available on which to make a judgment, he may request that additional studies be undertaken by the sponsoring agency or he may undertake an independent study of the problem.

Apollo Missions

- **Restricted Earth Return:** Apollo 11, 12, 14
 - *Quarantines of astronauts, lab team members, and other staff*
 - *Lunar Receiving Facility treated as equivalent BSL-3 or BSL-4 (before standardization of BioSafety Levels)*
 - *Animal testing and vivisection*
- **Unrestricted Earth Return:** Beyond Apollo 14

How much mass was brought back before NASA stopped the quarantine process?



Of the total mass of sample returned by the Apollo series, 25% of the total mass was brought back under quarantine

The “Whos”

- Responsibility was diffused through several agencies (Agriculture, Interior, and Health, Education, and Welfare), not an organizational issue confined to NASA.
- Voting members were all from these Agencies
- Non-NASA agencies had input into Baylor (biohazard test) Protocol.

Roles and Responsibilities of the ICBC

- NASA viewed the ICBC as advisory to NASA: The functions of the ICBC were limited to "advising," "recommending," "considering," and "reviewing" actions.
- Eleven members of the ICBC were specified, two from the Public Health Service (PHS), one each from Agriculture, Interior, and the National Academy of Sciences, and six from NASA.
- Chairperson and deputy chair were designated as PHS members, the executive secretary was designated as a NASA member.
- No voting procedures were specified.

1960-1969:

Foundations of lunar quarantine

(the abridged version)

- 1960** NAS advises NASA to form interagency committee on interplanetary quarantine “to formulate a national policy for handling spacecraft and material returned from other planets.”
- 1964** SSB convened conference on Back Contamination with USDA, Public Health Service, USDA, Fish and Wildlife Service, US Army, NIH, and NASA.
- 1965** NASA's Deputy Administrator proposed to Surgeon General that a formal liaison office with the Public Health Service be established, that a NASA-PHS advisory committee be set up to establish guidelines for back-contamination control and oversee NASA's efforts to avoid infecting the earth, and that the PHS recommend the kind of facilities and staff required to carry out those efforts.
- 1966**
April: ICBC officially meets for the first time.
October: ICBC meets at CDC to discuss designs for crew & sample labs
- 1967**
January: “Management Instruction: Assignment of Responsibility for Prevention of Contamination of Biosphere by Extraterrestrial Life” (MSCI 8030.1)
Feb: ICBC releases guidelines for handling lunar samples in quarantine
June: ICBC internal memo (Pickering to Hess) “Quarantine Schemes for Manned Lunar Missions”
July: Baylor Protocol
- 1968** February, June, November
- 1969**
March: ICBC discusses readiness related activities (e.g. simulated ops of LRL)
July: LRL Opens, Apollo 11 happens
November: Apollo 12

1970-1971:

From Lunar Quarantine to “All Clear”

1970

January: ICBC reviewed NASA administrator that crew quarantine be discontinued. They believed, however, that biological examination of the lunar samples should be continued and that biological containment practices in the lunar receiving laboratory should continue, since among other things they assured the integrity of the sample

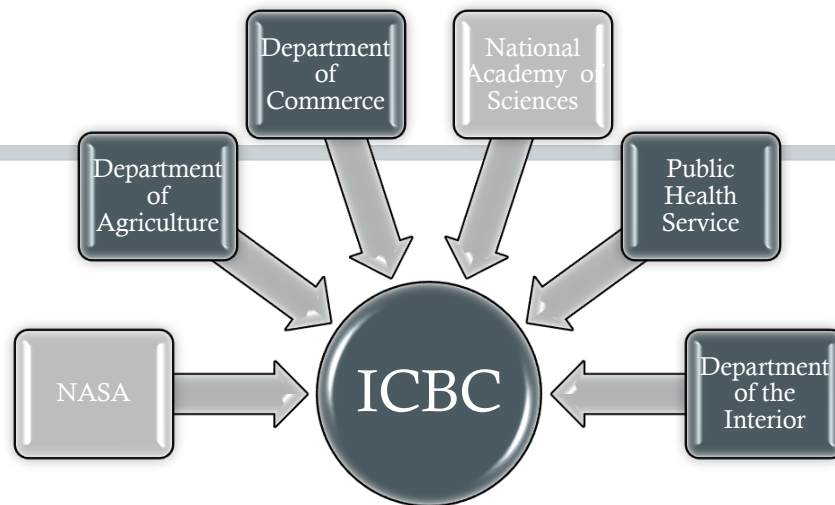
February: NAS Space Studies Board reviewed quarantine policy and found no reason to discontinue. *Space Science Board, National Academy of Sciences, "Report of Meeting on Review of Lunar Quarantine Program", February 17, 1970.*

1971

January: Apollo 14

May: Decision to discontinue lunar quarantine

Policies at the Time of Apollo



USDA:

- *Movement of Organisms*
- *Movement of Plant Pests*
- *Movement of Soil, Stone and Quarry Products*
- *Packaging and Shipment*

Commerce: Delegated transport to other agencies.

Public Health Service

- *Prevention of the introduction & spread of communicable diseases*
- *Foreign Quarantine*
- *Importation of Certain Things*
- *Interstate Importation*
- *Packaging and Shipment*

Dept. of Interior:

- *Commercial fishery resource disaster from undetermined causes*
- *Fish and Wildlife Act of 1956*

For Example:

Breadth of the Fish and Wildlife Act of 1956

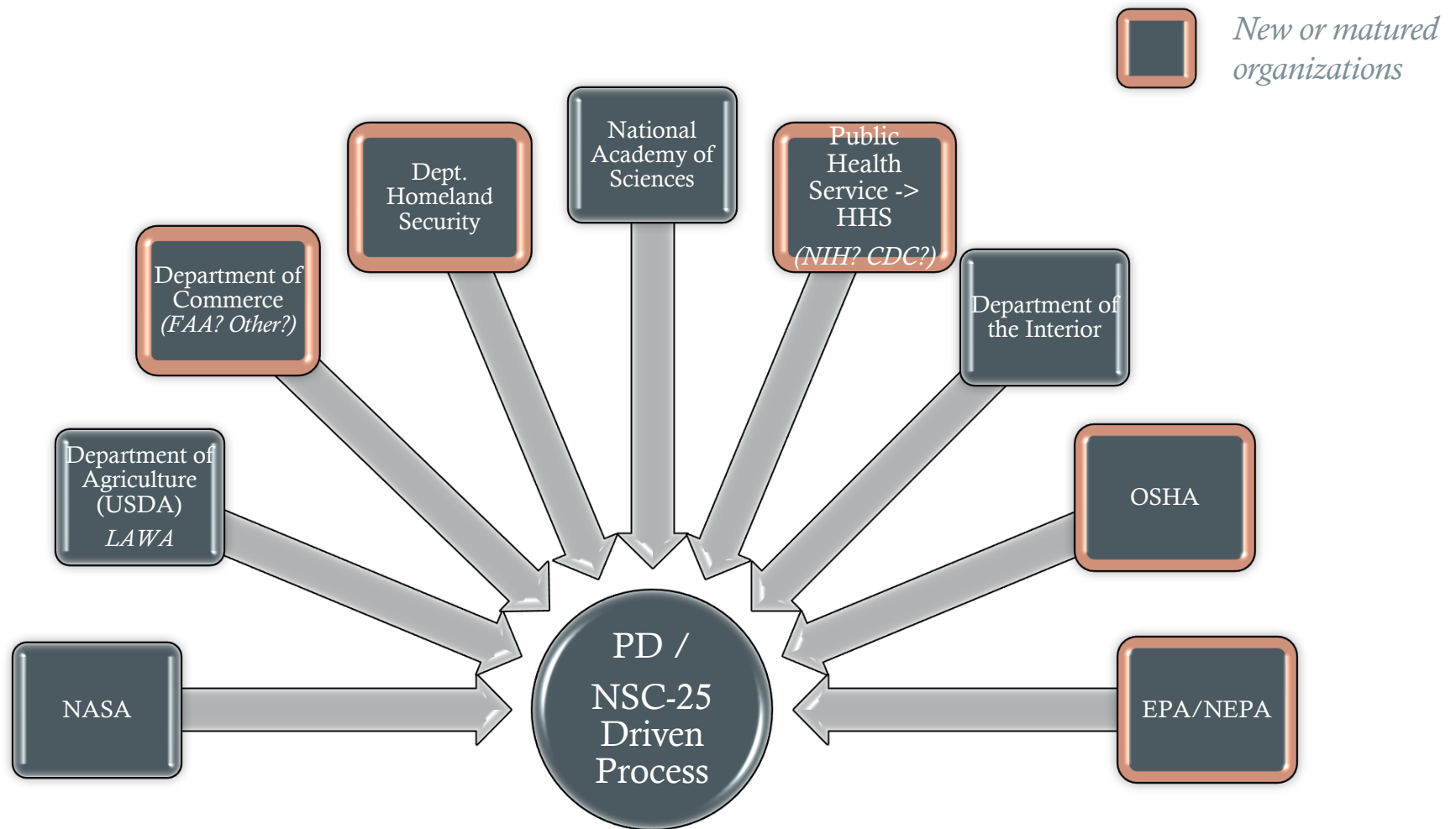
“The Secretary shall conduct investigations on the biological requirement of fish and wildlife resources and any other matters which the Secretary shall judge to be in the public interest in connection with any phase of fish and wildlife.”

Could a water landing for Apollo affect commercial fishing?

DoI had inputs into animal species and test inputs selected for the Baylor Protocol and technical input to use of Biological Isolation Garments (BIGs) in water.

Now...

PD/NSC-25 Driven Process and TBD Interagency Committee



Then and Now...Some Key Differences

A large number of Agencies with regulatory authority or interest that overlap with NASA (health, medical, environmental, occupational health) either did not exist or were coming into existence as Apollo 11, 12, and 14 missions were conducted.

Now, however, those agencies have well-established operating processes and organizational roles.

- **Could these now-matured organizations or the addition of other organizations lead to different degrees of discussion and negotiation for bounding the technical discussions on future 'Restricted Earth return' missions (and policy) that didn't exist in the Apollo era?**
- **Was this a "sweet spot," where the amount of requirements and conservatism was commensurate with the knowns and unknowns?**

PD/NSC-25

Presidential Directive National Security Council -25

- **1977, Carter Administration**
- **Why?** Primarily nuclear, sample return coverage here as well
- **Upshot:** Head of Agency requests President's approval via OSTP. (*akin to NSAM 235, though with a more formally described process for nuclear - INSRP and language changes*). Nuclear has its own process, which is explicitly stated now.
- **When has NASA used this?**
 - For Nuclear Missions: Galileo, Cassini, and MSL
 - Why: Concerns regarding potential legal liability were quite serious.
- **How (for nuclear):**
 - NASA convenes the INSRP (Interagency Nuclear Safety Panel) with DoD and DoE as members. EPA and NAS participate, as needed.
 - INSRP reviews mission hazards and writes Safety Evaluation Report (SER)
 - SER is provided to OSTP for information

THE WHITE HOUSE
WASHINGTON
December 14, 1977

UNCLASSIFIED
CONFIDENTIAL NOS

PRESIDENTIAL DIRECTIVE/NSC-25

TO: The Secretary of State
The Secretary of Defense
The Secretary of Energy
The Secretary of the Interior
The Secretary of Agriculture
The Secretary of Commerce
The Secretary of Health, Education, and Welfare
The Secretary of Transportation
The Acting Director, Office of Management and Budget
The Assistant to the President for National Security Affairs
The Chairman, Council on Environmental Quality
The Director, Office of Science and Technology Policy
The Director, Arms Control and Disarmament Agency
The Administrator, Environmental Protection Agency
The Administrator, National Aeronautics and Space Administration
The Director, National Science Foundation
The Chairman, Nuclear Regulatory Commission

SUBJECT: Scientific or Technological Experiments with Possible Large-Scale Adverse Environmental Effects and Launch of Nuclear Systems into Space (C)

Two earlier Presidential memoranda dealt with the conduct of scientific or technological experiments that might have large-scale or protracted effects on the physical or biological environment (NSAM 235 of April 17, 1963) and the launching into space of systems involving nuclear power (NSAM 50 (revised) of April 10, 1965). These two NSAMs are hereby rescinded. The general purpose, however, behind these two directives--to give the President the opportunity to consider all factors before any such experiment is carried out--remains valid. The President has approved the policy and procedures below to accomplish that purpose.

It should be understood that experiments which by their nature could reasonably be expected to result in domestic or foreign allegations that they might have major and protracted effects on the physical or biological environment,

UNCLASSIFIED
CONFIDENTIAL NOS

Declassified/Released on 9/5/05
under provisions of E.O. 12356
by D. Rieker, National Security Council

Need to look at all experiments that might have major/protracted effects on physical/biological environment...even if the “agency feels confident that such allegations would prove in fact to be unfounded...”

It should be understood that experiments which by their nature could reasonably be expected to result in domestic or foreign allegations that they might have major and protracted effects on the physical or biological environment,

or other areas of public or private interest, are to be included under this policy even though the sponsoring agency feels confident that such allegations would in fact prove to be unfounded.

“might” and “may” are enough....

1. The head of any agency that proposes to undertake a large-scale scientific or technological experiment that might have major and protracted effects on the physical or biological environment, or on other areas of public or private interest, will call such proposals to the attention of the Director of the Office of Science and Technology Policy (hereafter the Director). The Director will consult with the Chairman of the Council on Environmental Quality (hereafter, the Chairman). Notification of such experiments will be given sufficiently in advance that they may be modified, postponed, or cancelled, if such action is judged necessary in the national interest.

7. Any large scale scientific or technological experiment that may involve particularly serious or protracted adverse effects will not be conducted without the President's approval. Any experiment that may involve serious or protracted adverse effects will not be conducted without the approval of the head of the department or agency involved, with, in appropriate cases, the advice of other concerned agencies.

8. To the extent that it is consistent with national security, and subsequent to approval of the experiment, there should be early and widespread dissemination of public information explaining the purpose, benefits, and assessments of impacts.

Process:

1. Agency head notifies OSTP Director of proposed experiment
2. OSTP director consults with CEQ/EOP
3. Agency will prepare evaluation of experiment's importance and environmental effects (NEPA).
4. Proposal info is reviewed by OSTP and CEQ chair, who determine action.
6. State Department may be notified if there is foreign impact to be considered.

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2. In support of proposals for such experiments, the sponsoring agency will prepare for the Director a detailed evaluation of the importance of the particular experiment and the possible direct or indirect environmental effects that might be associated with it. The data from an environmental impact statement may be used in complying with this procedure.

3. The Director in consultation with the Chairman will review the proposals and supporting materials presented by the sponsoring agency in order to assure that the need for the experiment has been properly weighed against possible adverse effects.

4. On the basis of this review, the Director in consultation with the Chairman will recommend to the President what action should be taken on the proposed experiment. If the Director, in consultation with the Chairman, judges that inadequate information is available on which to make a judgment, the Director may request that additional studies be undertaken by the sponsoring agency or may undertake an independent study of the problem. Agencies will be notified if an extended delay is anticipated in approval.

6. While the final decision to conduct such experiments must continue to reside with the government, the National Academy of Sciences and, where appropriate, international scientific bodies or intergovernmental organizations may be consulted in the case of those experiments that might have adverse effects beyond the US. When experiments are expected to have such impacts in foreign countries the Secretary of State will be notified. In arriving at decisions on specific projects, foreign policy considerations should be taken into account. Recommendation on the advisability of the courses of action will be made by the Director in consultation with the Chairman and with the sponsoring agency and the State Department as appropriate.

1960-1969:

Foundations of lunar quarantine

Black = Events in the Apollo Quarantined Return Era

Red = Areas/Agencies that have appeared or matured since Apollo sample return

- 1960** NAS advises NASA to form interagency committee on interplanetary quarantine “to formulate a national policy for handling spacecraft and material returned from other planets.”
- 1964** SSB convened conference on Back Contamination with USDA, Public Health Service, USDA, Fish and Wildlife Service, US Army, NIH, and NASA.
- 1966** *Laboratory Animal Welfare Act*
- 1967** **January:** “Management Instruction: Assignment of Responsibility for Prevention of Contamination of Biosphere by Extraterrestrial Life” (MSCI 8030.1)
Feb: ICBC releases guidelines for handling lunar samples in quarantine
June: ICBC internal memo (Pickering to Hess) “Quarantine Schemes for Manned Lunar Missions”
July: Baylor Protocol
- 1969** *NEPA passed and Council on Environmental Quality founded (White House)*
CDC issues Classification of Agents on the Basis of Hazards
July: LRL Opens, Apollo 11 happens
November: Apollo 12

1970-1971:

From Lunar Quarantine to “All Clear”

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February: NAS Space Studies Board reviewed quarantine policy and found no reason to discontinue. *Space Science Board, National Academy of Sciences, "Report of Meeting on Review of Lunar Quarantine Program, February 17, 1970."*

December:

- EPA founded
- OSHA established
- LAWА amended and renamed Animal Welfare Act

1971

January: Apollo 14

May: Decision to discontinue lunar quarantine

1972-Present:

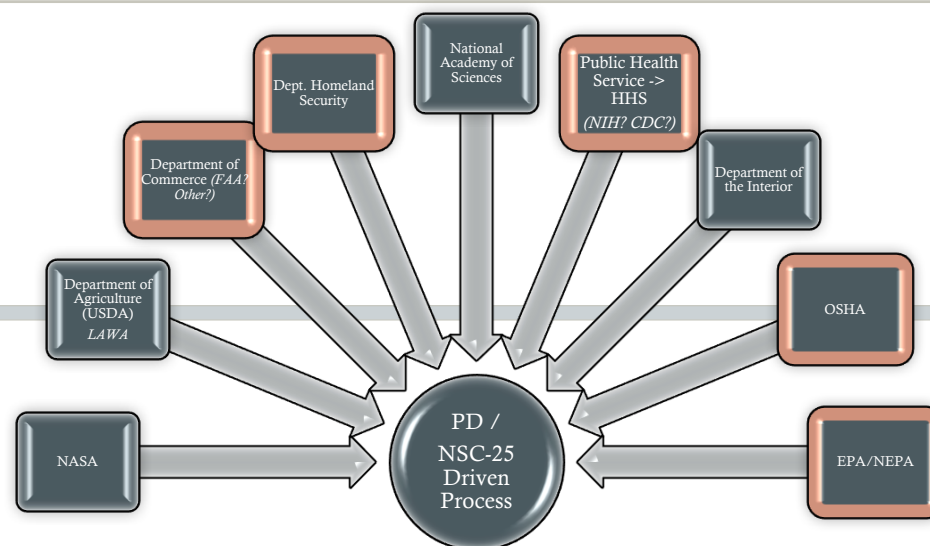
As Science Evolves, Policy and Agency Governance Grows

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1976	OSTP Founded
1977	PD NSC-25
1984	Establishment of BSL 1-4 Criteria
1985	Nat Sec Council Decision Directive 189
1999	Exec Order for Dept of Interior: Invasive Species
2003	Select Agent Policy Established Dept. Homeland Security Founded
2012/2014	DURC/GoF Requirements (NSABB/DHS)

Now...



USDA:

- Movement of Organisms
- Movement of Plant Pests
- Movement of Soil, Stone and Quarry Products
- Packaging and Shipment
- *LAWA, amended (Baylor Protocol impact)*

Public Health Service/NIH/CDC

- Prevention of the introduction & spread of communicable diseases
- Foreign Quarantine
- Importation of Certain Things
- Interstate Importation
- Packaging and Shipment
- *DUR/DURC or Equivalent?*
- *Biosecurity*

EPA: NEPA process (with NASA input)

OSHA: Possible coverage “including those created by new technology”

Dept. of Interior:

- Commercial fishery resource disaster from undetermined causes
- Fish and Wildlife Act of 1956
- *Invasive Species*

DHS? DoD?

Questions

- Who was involved with back contamination for the first rounds of Apollo missions?

What agencies?

Who selected these agencies?

Terms of Reference?

- **Was there any overlap in quarantine policy development and requirements for robotic missions vs. Apollo (forward and backward contamination)? If so, where and how much?**
- Who determined when there was enough evidence to deem lunar samples “safe” and crew members “safe” from potential lunar biohazards with terrestrial-equivalent mechanisms?

Forward and **Backward** Contamination:

Separate Tracks (1/2)

- 1958** NASA comes into existence.
- National Academy of Sciences (NAS), NSF and American Institute of Biological Sciences & the National Science Foundation meeting to discuss spacecraft sterilization
- West Coast Committee on Extraterrestrial Life (WESTEX) met to address preserving & protecting planetary surfaces during exploration.
- 1959** NAS advises NASA to sterilize spacecraft. Ranger Program starts.
- 1960** NASA creates Office of Life Sciences. NAS advises NASA to form interagency committee on interplanetary quarantine “to formulate a national policy for handling spacecraft and material returned from other planets.”
- 1961** Ranger Lunar Missions start implementation of sterilization of hardware.
- Administrator-approved protocol is: (1) pre-assembly, all components and heat sterilize (125°C/24 hrs); (2) assemble sterilized components and test in a clean facility, cleaning all surfaces to be joined with alcohol); (3) Ship to the Cape in a controlled environment, conduct pre-launch tests and soak after in EtO in the fairing.*

Forward and **Backward** Contamination:

Separate Tracks (2/2)

- 1963** NSAM 235 written.
- NASA “Interim Requirements for Bioclean Facilities” issued.**
- 1964** SSB convened conference on Back Contamination with USDA, Public Health Service, USDA, Fish and Wildlife Service, US Army, NIH, and NASA.
- Heat Sterilization discontinued for Ranger 6-9, though EtO still in use.**
- 1965-1967** Negotiations between NASA and Public Health Service on roles and responsibilities.
- NASA issues “Procedures Manual for Planetary Spacecraft to be Sterilized by Heating.”**
- 1966** Voyager Project starts. Plans include heat sterilization of components (125C/53 hrs) and system-level EtO (initial plan was to go to Mars)
- 1967** Interagency Committee on Back Contamination (ICBC) is formed and formalized as an interagency agreement. Baylor Protocol issued.
- Issue of NPD 8020.8, "Outbound Lunar Biological Contamination Control: Policy and Responsibility."**

Questions

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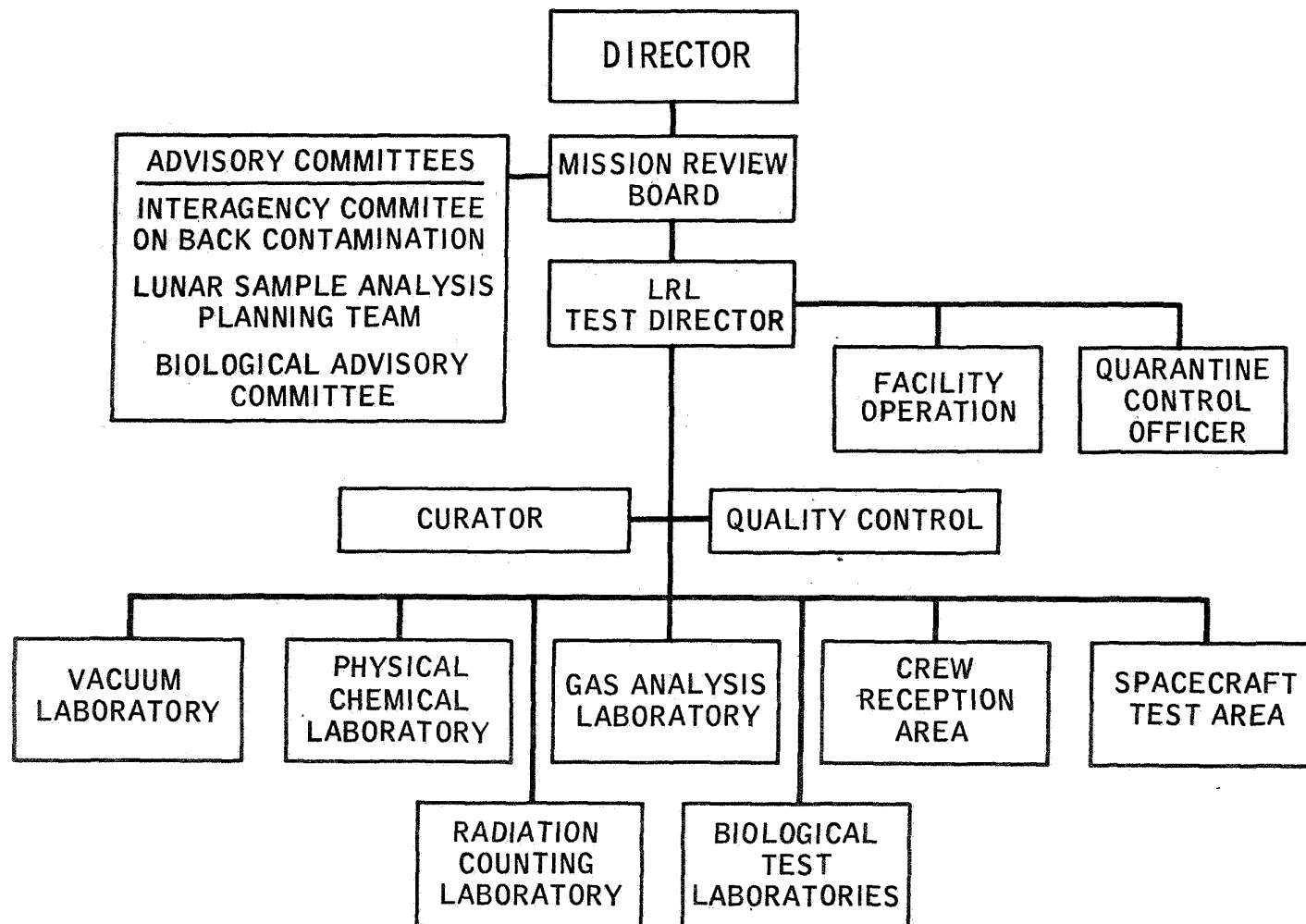
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LRL MISSION ORGANIZATION



Assumptions

1. The existence of hazardous, replicating microorganisms on the moon would be assumed.
2. The preservation of human life should take precedence over the maintenance of quarantine.
3. Biological containment requirements should be based on the most stringent methods used for containment of infectious terrestrial agents.
4. The sterilization requirement should be based on methods needed for the destruction of the most resistant terrestrial forms.
5. Hazard detection procedures should be based on an alteration of the ecology and classical pathogenicity .
6. The extent of the biological test protocol would be limited to facilities approved by the Congress, to well-defined systems, and to biological systems of known ecological importance.

Conditions for Release of Samples from Containment in LRL/JSC

After execution of the Baylor Protocol:

Proposition I: Samples show **negative results** = no viable organisms isolated and no pathogenic effects in plants and animals tested

Proposition II: Samples show **positive results** = replicating organism detected *without* deleterious results on life systems or biological niches tested in LRL.

Proposition III: Samples show **positive results** = replicating organism detected *with* deleterious effects on one or more plant or animal systems tested in LRL.

Conditions for Release of Samples from Containment in LRL/JSC

Proposition I: Samples show **negative results** = no viable organisms isolated and no pathogenic effects in plants and animals tested

Un/Conditional Release after review by ICBC and regulatory authorities

Proposition II: Samples show **positive results** = replicating organism detected *without* deleterious results on life systems or biological niches tested in LRL.

Un/Conditional Release:

- *If terrestrial and reviewed by ICBC and regulatory authorities*
- *If of unknown origin, sterilized and reviewed by ICBC*

Proposition III: Samples show **positive results** = replicating organism detected *with* deleterious effects on one or more plant or animal systems tested in LRL.

Un/Conditional Release if:

- *it had an effect in the Baylor organism*
- *seems to be replicating*
- *and is non-pathogenic...*

ICBC reviewed data & action prior to:

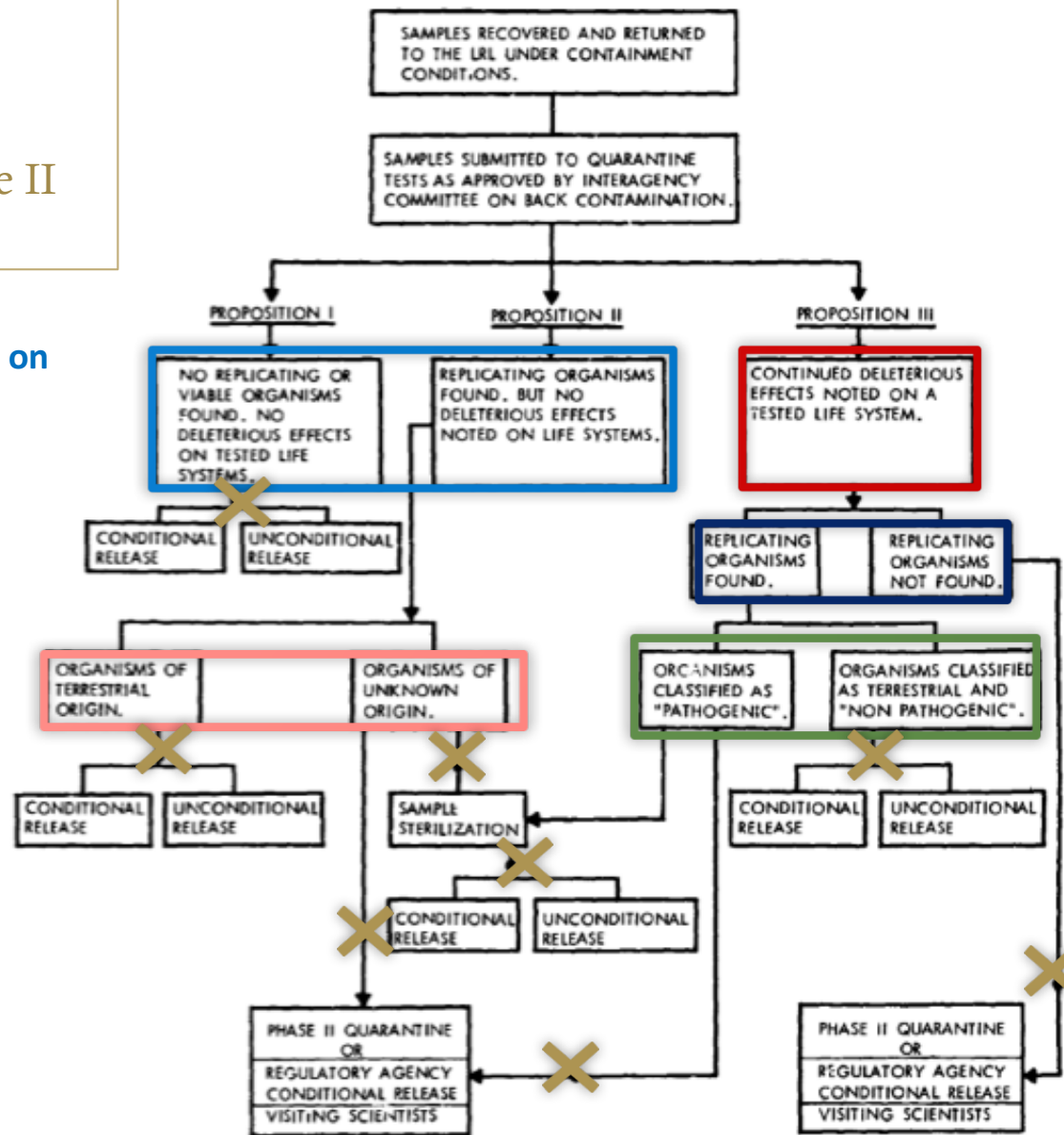
- Any release
- Sterilization
- Or move to Phase II quarantine

No deleterious effects on
Baylor test systems.

Is it replicating?

Is it terrestrial?

TABLE II. QUARANTINE SCHEME FOR RETURNED LUNAR SAMPLES (PHASE I)



Deleterious
effects on Baylor
life test system.

Replicating?

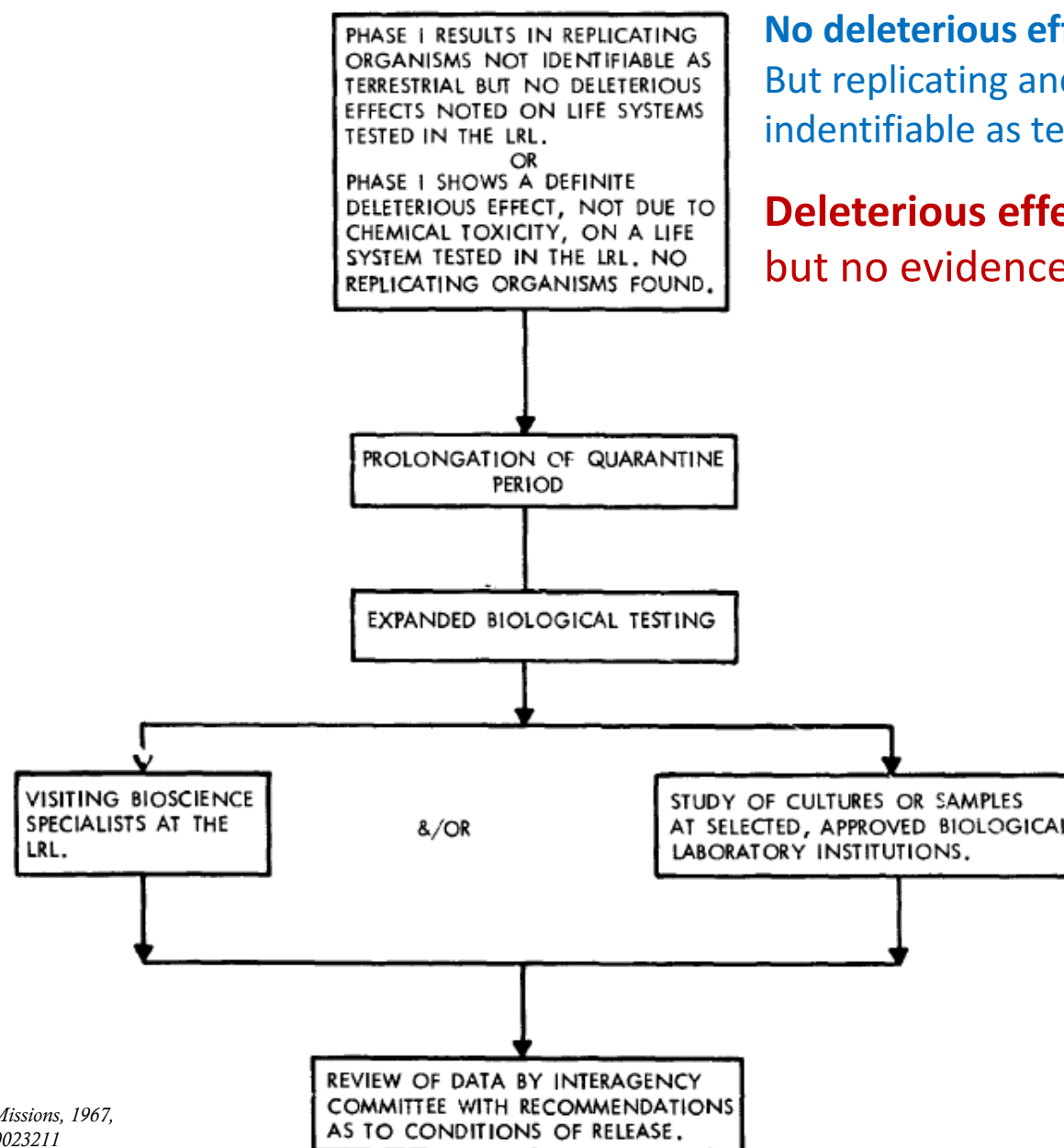
Pathogenic?



INDICATES:

- REVIEW OF DATA AND PROPOSED ACTION BY THE INTERAGENCY COMMITTEE ON BACK CONTAMINATION, AND
- FORMAL CLEARANCE BY THE REGULATORY AGENCIES, WHEN NECESSARY.

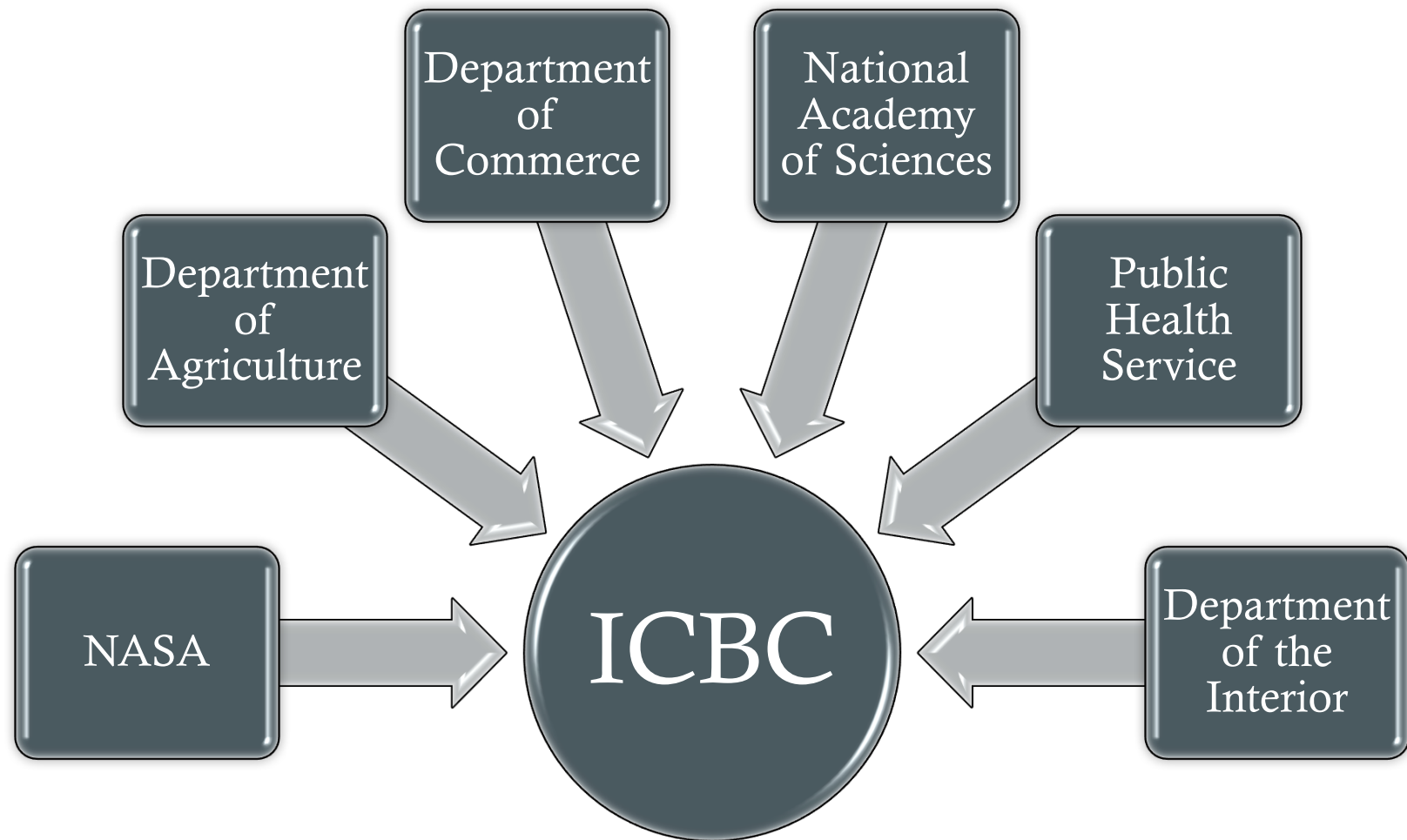
TABLE III. QUARANTINE SCHEME FOR RETURNED LUNAR SAMPLES (PHASE II)



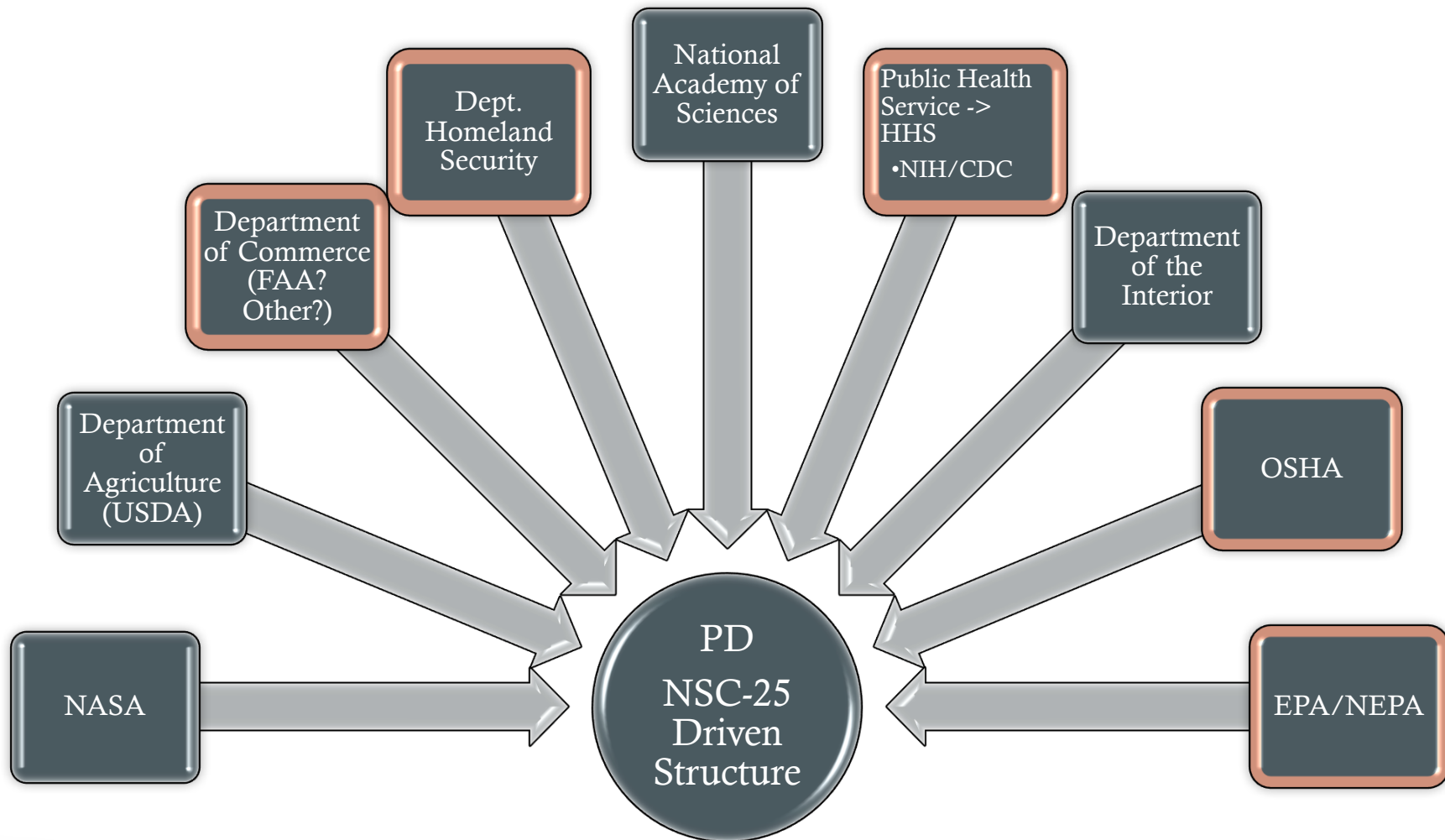
No deleterious effect,
But replicating and not
identifiable as terrestrial

Deleterious effect,
but no evidence of replication.

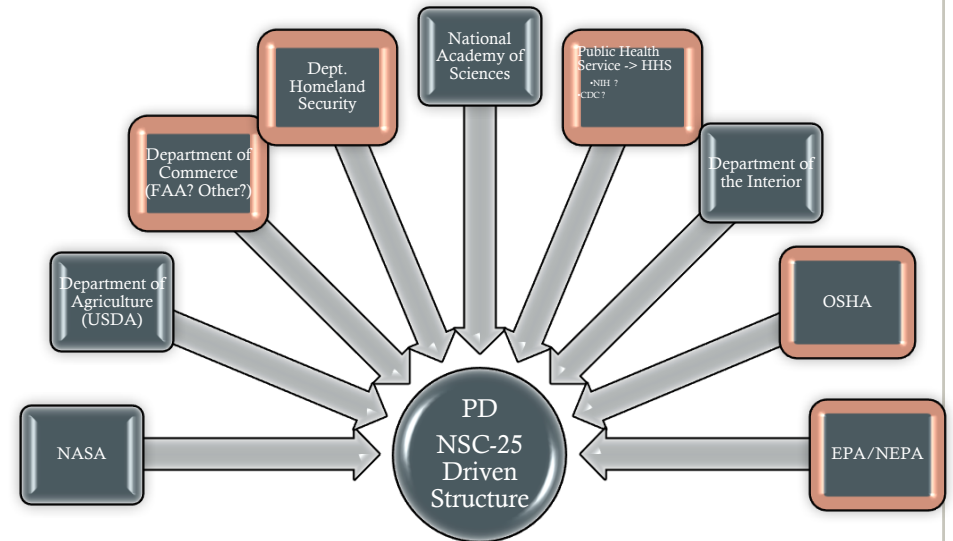
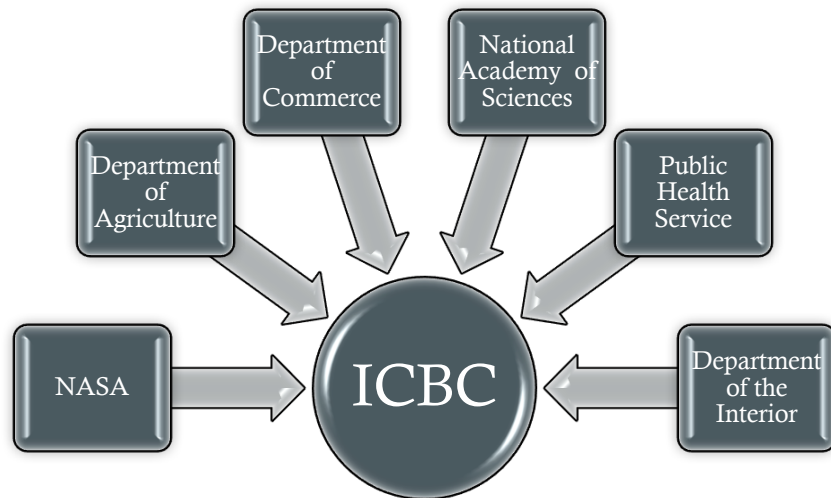
Then...



Now...



Was Apollo Sample Return conducted in a “sweet spot”?



Backup Slides

OSHA—then and Now

- **OSHA came into existence just after Apollo 11 (January 1970).**
- **Its focus for Apollo was environmental exposures (noise, vibration, etc.)**
- **Could it extend its coverage to safety in handling returned samples?**

*Occupational Safety and Health Act of 1970 (29 U.S.C. 653) [29 U.S.C. 651 et seq.] § 669.
Research and related activities (a) Authority of Secretary of Health and Human Services to
conduct research, experiments, and demonstrations, develop plans, establish criteria, promulgate
regulations, authorize programs, and publish results and industry- wide studies; consultations*

*(4) The Secretary of Health and Human Services shall also conduct special research,
experiments, and demonstrations relating to occupational safety and health as are necessary to
explore new problems, including those created by new technology in occupational safety and
health, which may require ameliorative action beyond that which is otherwise provided for in the
operating provisions of this chapter.*

Department of Interior

- At the time of Apollo, DoI started discussions on invasive species and Environmental Quality.
- Changing role with Invasive Species Executive Orders: 1999 and 2016
[Executive Order 13112 of February 3, 1999 (Invasive Species) and Executive Order 13751 of December 5, 2016]
- Definitions in EOs are very broad:
 - (a) "Alien species" means, with respect to a particular ecosystem, any species, including its seeds, eggs, spores, or other biological material capable of propagating that species, that is not native to that ecosystem.
 - (f) "Invasive species" means an alien species whose introduction does or is likely to cause economic or environmental harm or harm to human health.
 - (h) "Species" means a group of organisms all of which have a high degree of physical and genetic similarity, generally interbreed only among themselves, and show persistent differences from members of allied groups of organisms.

Department of Interior

- 3) not authorize, fund, or carry out actions that it believes are likely to cause or promote the introduction or spread of invasive species in the United States or elsewhere unless, pursuant to guidelines that it has prescribed, the agency has determined and made public its determination that the benefits of such actions clearly outweigh the potential harm caused by invasive species; and that all feasible and prudent measures to minimize risk of harm will be taken in conjunction with the actions.
- Also has a Council akin to PPS

Selected References

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