RASH

Regulatory Activity Submission Hierarchy
Proposal Overview

RASH: What's it all about?

- A structured document
- Adjunct to RPS
- Describe the *Hierarchical Structure* of a submission (aka Regulatory Activity)
- Provide all (hopefully) of the rules needed to construct a submission TOC
  - For the sponsor: Build an RPS message that looks like a submission TOC
  - For the reviewer: interpret an RPS message into a TOC

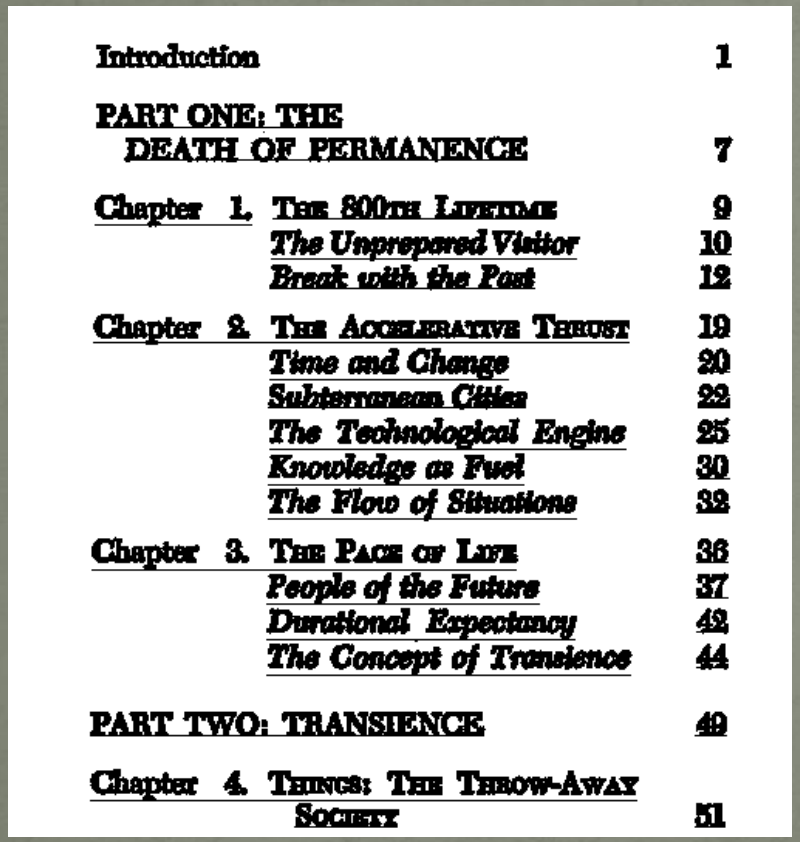
RASH is proposed to be a ***machine-readable implementation guide*** *for RPS*

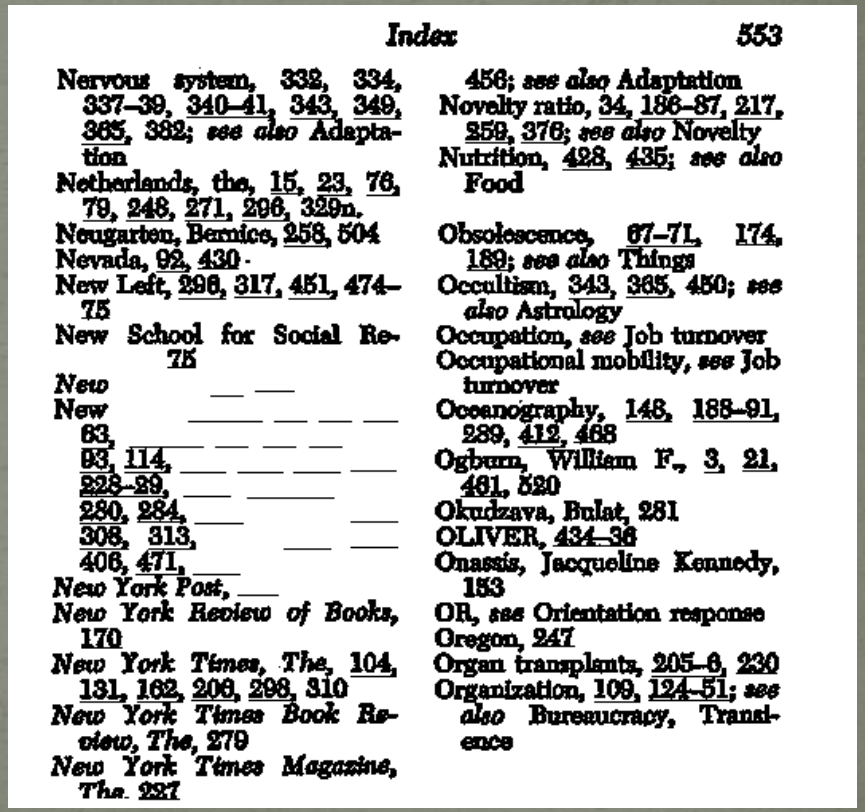
Why is RASH Needed?

1. RPS doesn't convey the structure
2. Provide an open format for communicating changes
3. Eliminate some of the validation confusion

RPS Structure

- eCTD is a Table of Contents
- RPS is an Index





RPS Structure

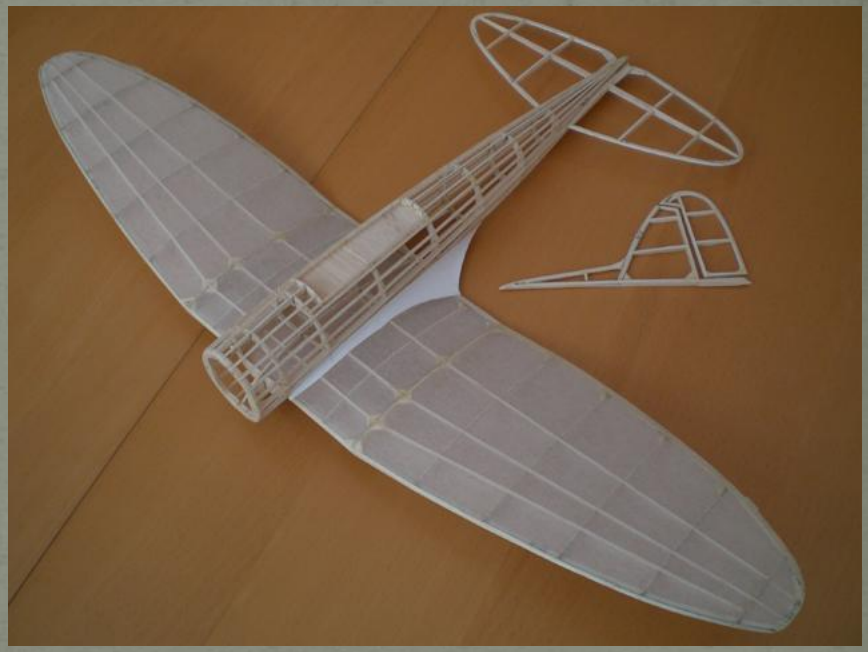
- Submission creators don't want to make an index
  - They want to create a submission TOC
- Submission reviewers don't want to navigate the index
  - They want to look at a submission TOC
- *RPS alone doesn't provide the shape of the TOC for a given submission type*

For reviewers, RASH is…

- A way of extruding an RPS message into a submission-specific organization
  - A different shape is needed for each submission type

For Submission Assembly, Rash Is…

- A structure to hang the submission components onto
  - It's the instructions of what comes in what order for each submission type



This isn't a new problem

- eCTD has evolved since 2003
  - New versions don't require new software
  - Mostly
  - But this is only to support one Regulatory Activity: eCTD
  - Each Region's Module 1 has specific requirements
- Every vendor has their own means of loading new versions
- Differences in interpretation cause validation issues
  - This is why ETICS was needed, and IRISS-Forum was formed
- Having to do this from scratch for each submission type would be expensive

How to Communicate Codes?

- Currently, NCI has RPS codes for US CTDs
  - A list of Context of Use Codes
  - A list of keyword types
  - etc.
- There is no relationship between the Context codes and the keywords
- There is no indication of which ones are needed for which submission types

What questions could RASH answer?

- What submission types does this hierarchy include?
- Where does a given Context of Use fit in a TOC?
- How many of a given Context of Use can be in a submission?
  - Cover Letter is required, but only one
  - Clinical Reports are optional, but could be many
- What is the default file name for a Context of Use?
- What keywords are valid for a Context of Use
  - Are they required or optional?
  - Are they only for some sub-types of the submission?
    - "Private" data for Master Files
  - What code list?
  - How do they get grouped? (e.g. studies within indication)
- What kind of file goes into this Context?
  - Graphics, Datasets, etc. go in specific places

Validation using RASH

- Codes used are valid for the submission type
- Not duplicated if only one permitted
- Not missing if required
- Contains the right set of keywords
- Correct file type was used
- Correct file name was used

Who owns the RASH data?

- Each Regulatory Authority should own its own submission types
- Hopefully, there will be “common” sets that can be used internationally
  - Sponsors would prefer to have one code for the same file submitted to multiple regions
  - One CTD set, for instance, should enable many submission types
  - An “Include” operation is critical
    - It may be necessary to have an “Include everything except” or “Include only” operation

Should it be part of the RPS Project?

- It's the right set of people
- RPS has a full schedule
- More technical resources may be needed

- *Basically, I'm not fussy. I want to see it done, however it gets done*