

Add language as an attribute to indicate correspondence language preferred or make it a set of allowable languages (EU).

BRIDG Release 2.1 – Static Classes::Organization

- + country: DSET <CD>
- + description: ST
- + identifier: DSET <I>
- + languageCode: DSET <CD>
- + name: DSET <ENON>
- + postalAddress: AD
- + statusCode: CD
- + statusDateRange: IVL <TS>
- + telecomAddress: DSET <TEL>
- + typeCode: CD

Include information on contacts for organizations associated with the application.

BRIDG Release 2.1 – Static Classes::RegulatoryApplicationSponsor

```

::Organization
+ country: DSET <CD>
+ description: ST
+ identifier: DSET <I>
+ languageCode: DSET <CD>
+ name: DSET <ENON>
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL <TS>
+ telecomAddress: DSET <TEL>
+ typeCode: CD
  
```

BRIDG Release 2.1 – Static Classes::RegulatoryAuthority

```

OversightAuthority
::Organization
+ jurisdictionCode: CD
+ country: DSET <CD>
+ description: ST
+ identifier: DSET <I>
+ languageCode: DSET <CD>
+ name: DSET <ENON>
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL <TS>
+ telecomAddress: DSET <TEL>
+ typeCode: CD
  
```

BRIDG Release 2.1 – Static Classes::RegulatedProduct

```

+ approvalIdentifier: DSET <I>
+ approvalStatusCode: CD
+ authorizationTypeCode: CD
+ expandedAccessStatusCode: CD
  
```

BRIDG Release 2.1 – Static Classes::RegulatoryApplication

```

+ identifier: II
+ typeCode: CD
  
```

SubmissionRegulatedProductRelationship

```

+ dateRange: date
  
```

KeywordDefinition

```

+ code: CD
+ value: ST
  
```

DocumentationTarget

```

+ documentReferenceIdentifier: int
+ regulatoryAuthorityIdentifier: int
  
```

SubmissionRegulatoryApplicationRelationship

KeywordsAssociated

```

+ textExplanation: ST
  
```

DocumentLogicalClassification

```

+ classificationTypeCode: CD
+ languageCode: ST
+ status: CD
+ version: ST
  
```

Clarifying with the BRIDG THC: Keyword Definition and Keyword are both in the RPS R1 RMIM, but are not in the BRIDG model. KeywordDefinition has a many to many relationship with DocumentLogicalClassification realized by the KeywordsAssociated.

BRIDG Release 2.1 – Static Classes::ReviewableUnit

```

::Submission
+ assessmentDateRange: IVL <TS>
+ identifier (RegulatoryAuthority assigned): ST
+ receiptDate: TS
+ regulatoryAssessmentCode: CD
+ typeCode: CD
  
```

BRIDG Release 2.1 – Static Classes::Submission

```

+ assessmentDateRange: IVL <TS>
+ identifier (RegulatoryAuthority assigned): ST
+ receiptDate: TS
+ regulatoryAssessmentCode: CD
+ typeCode: CD
  
```

BRIDG Release 2.1 – Static Classes::SubmissionUnitRelationship

```

«StudyRelationship»
+ identifier: II
+ typeCode: CD
  
```

organizationContactPerson

```

+ address
+ contactType
+ name
  
```

contactMethod

```

+ type
+ value
  
```

BRIDG Release 2.1 – Static Classes::SubmissionUnit

```

+ receiptDate: TS
+ serialNumber: ST
+ statusCode: CD
+ statusDateRange: IVL <TS>
+ typeCode: CD
  
```

NEW ATTRIBUTES:
category
subcategory
date sent
date received
subject
description
sponsor submission unit identifier
sponsor serial number (order)

DocumentReference

```

+ associatedAction: CD
+ comment: ST
+ referenceID?
  
```

DocumentFile

```

+ description: ST
+ fileName: ST
+ fileType: CD
+ language: SET?
+ physicalLocation?
+ uniqueIdentifier: int
  
```

BRIDG Release 2.1 – Static Classes::Document

```

+ bibliographicDesignation: ST
+ keywordCode: DSET <CD>
+ keywordText: ST
+ languageCode: CD
+ officialTitle: ST
+ publicDescription: ST
+ publicTitle: ST
+ revision: ST
+ scientificDescription: ST
+ text: ST
+ typeCode: CD
+ universalResourceLocator: TELURL
  
```

Language: Document needs a language attribute. Does it need to allow multiple associated languages (e.g., French AND German)?

Clarifying with the BRIDG THC: The current BRIDG model has a DSET attribute for keywords but nothing to define or constrain the set by application (as implied by the RMIM). Is this intentional?

The combination of the generalization and composition relationship implies the following:
• A Reviewable Unit is a type of Submission
• A Submission may be composed of Reviewable Units
A Reviewable unit inherits the many to many relationship with Submission Unit through the Submission superclass so it has the same basic logical relationship as Package Group. RPS R1 handles this without modification.

Relationship changed to resolved many-to-many: Submission Unit should allow references or instructions for multiple documents. If replace, need to say which one.

(Resolved many-to-many relationship). Especially for devices, the Submission (aka Regulatory Activity) may apply to many products and vice versa. Should this relationship be at the Submission level or at the Regulatory Application (aka Dossier) level?

EU, Canada: Documentation is targeted toward one or many agencies

Correspondence Language: Added as languageCode to Organization to allow association of multiple languages with the Organization.

SubmissionUnit adds or removes contacts for the organizations. The contacts ultimately relate to the Submission.

Changed from composition to many to many.

is associated to a submission via / associates a submission to

associates a submission unit to / is associated to a submission unit via

1 is the parent of

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